REGULATORY REQUIREMENTS OF H.R. 1415,
"The Patient Access to Responsible Care Act"

March 10, 1998

MULTINATIONAL BUSINESS SERVICES, INC.
11 Dupont Circle, N.W.
Suite 700
Washington, D.C. 20036
(202) 293-5886
Executive Summary

Multinational Business Services, Inc. ("MBS") was asked by the the Health Benefits Coalition to assess the costs that H.R. 1415/H.R. 2960, the "Patient Access to Responsible Care Act" ("PARCA"), introduced by Congressman Charles Norwood (R-GA), would impose on the Federal Government, State governments, employers offering group coverage, insurers and managed care entities.

Specifically, MBS addressed the following issues, and arrived at the following conclusions:

- **New Regulatory Mandates:** PARCA would impose a total of 207 new regulatory mandates on the public and private sectors, based on the narrow definition of "mandate" found in the Unfunded Mandates Reform Act of 1995. See pages 6-8 and 31-52.

  Because State governments would be subject to as many as 91 of these mandates, depending on the extent to which responsibility would be shared between the Federal and State governments (see discussion at page 7), PARCA could result in the imposition of more than 1,000 new mandates on the public sector as a whole.

- **Distribution of New Mandates:** The 207 new mandates would be imposed on the following groups:

  -- Health insurance issuers (e.g., employers, insurers, managed care entities) providing coverage through provider networks: 108 new mandates. See pages 31-42.
  -- Health insurance issuers (e.g., employers, insurers, managed care entities) providing non-network coverage: 61 new mandates. See pages 31-38.
  -- State governments: 91 new mandates, to the extent that individual States decide to assert their authority to regulate (see Mandate #201 at page 52 and pages 43-51), as well as 6 additional, State-specific mandates. See Mandates ##202-207 at page 52.

- **Windfall Benefits:** Although Congressman Norwood has characterized his bill as "patient" protection legislation, in fact, 34% of the new burdens to be imposed on health plans (at employer, employee, enrollee and taxpayer expense) (i.e., 37 of the 108 health insurance issuer
mandates) are designed to protect "health professionals and providers," not patients. Only 15% of the new health insurance issuer mandates (i.e., 16 out of 108) are designed solely to protect patients. See pages 8-9.

- **New Federal Hires:** The Federal Government would have to hire a minimum of 3,828 new full-time employees ("FTEs") to implement and enforce PARCA. To the extent that States undertake implementation and enforcement, the Federal burden could be somewhat decreased, but it is unlikely that the States would have the resources for adequate enforcement, so that, by law, the Federal Government would have to undertake oversight as the automatic fallback. See pages 10-14.

- **Required Annual Appropriations:** Annual appropriations to the Departments of Labor and Health and Human Services ("HHS") would have to be increased by a minimum of $155,294,304.00. See pages 10-14.

- **New Federal Regulations:** The Departments of Labor and HHS would have to jointly promulgate 60 new regulations to implement the 207 new mandates. Each regulation would have to cover a number of different healthcare delivery factual scenarios. Even if all 60 new rulemakings were consolidated into one administrative proceeding, the magnitude of the regulatory effort that would be required in order for PARCA to become operational is immense. See pages 15-21.

- **New Federal Causes of Action:** PARCA would create 33 new Federal-law causes of action that do not presently exist in American jurisprudence. All of these new causes of action would be subject to the jurisdiction of the Federal courts. (The new Federal burdens and costs associated with this litigation were not taken into account in estimating new Federal FTEs and appropriations above; therefore, those estimates are lower than what would actually occur if PARCA were enacted.) See pages 22-25. Plaintiffs in the 33 new causes of action would be providers and enrollees.

- **Impact of the 33 New Federal Causes of Action on the Healthcare Delivery System:** Assuming that only 3% of providers (including providers who are disgruntled because they were rejected for participation in certain provider networks on quality or past-performance grounds), and only 0.015% of enrollees file lawsuits, the result would be 247,944 new Federal lawsuits per year. The costs
associated with these lawsuits would be translated into higher premiums and reduced coverage. See pages 25-27.

- **New Exposure to State-Law Claims Under ERISA:** PARCA would expose ERISA plans to three new types of legal liability under State law. Based on current malpractice costs, MBS estimates that defending meritless claims and damages payouts would add annual costs of $986,879,368.00 to the healthcare delivery system. The costs associated with these lawsuits would be translated into higher premiums and reduced coverage. See pages 28-30.

- **New Kinds of State-Law Claims:** New State-law claims would include: (1) being brought into existing medical malpractice and other State-law liability litigation by providers looking for "deep pockets"; (2) claims against health insurance issuers based on utilization review determinations; and (3) claims against health insurance issuers based on coverage determinations. See page 28.
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Introduction

THE NORWOOD BILL

H.R. 1415 (the "Patient Access to Responsible Care Act," or "PARCA"), introduced by Congressman Charles Norwood (R-GA), would amend the Public Health Service Act and the Employee Retirement Income Security Act of 1974 ("ERISA") by enacting a series of "Patient Protection Standards" that would be applicable to all group and individual insurance offered in the private market. In addition, H.R. 1415 would make "health insurance issuers" (a category which includes employers offering group coverage, insurers and managed care entities) liable for State law liability claims such as medical malpractice.

H.R. 1415's companion bill, H.R. 2960, also introduced by Congressman Norwood, would expand the State law claims for which "health insurance issuers" under ERISA would be liable to include:

- personal injury claims;
- financial injury claims; and
- wrongful death claims.

In addition to exposing health insurance issuers to increased liability claims under ERISA, PARCA's "patient" protections would enact a new regime of provider rights against health plans. These new provider rights would require an overhaul of virtually every aspect of health plan administration in the U.S., and would result in the imposition of whole categories of new costs to the U.S. healthcare delivery system. Despite the significant impact that PARCA would have on the entire private health insurance market, the public debate on PARCA has not yet focused on all of the specific impacts PARCA would have on the ability of employers, insurers and managed care entities to provide healthcare services on a daily basis.

Finally, PARCA would impose significant new costs on the Federal and State Governments, which have not yet been fully assessed in the public debate over PARCA. These costs would include ongoing rulemaking requirements, as well as necessary investigation and enforcement activities.
THE GOALS OF THIS STUDY

In light of the wide-ranging impacts PARCA would impose, Multinational Business Services, Inc. ("MBS") was asked by the Health Benefits Coalition to assess the financial and other costs PARCA would impose on the Federal Government, as well as on health insurance issuers. Specifically, MBS was asked to assess the following:

(1) **New Regulatory Mandates:**
- Using the definition of "mandate" found in the Unfunded Mandates Reform Act of 1995, how many regulatory mandates would be imposed by PARCA?
- Which groups would be directly responsible for compliance with these mandates?
- Who is intended to be protected by these mandates?
- See Chapter One.

(2) **New Federal Hires and Appropriations:**
- How many new full-time employees ("FTEs") would have to be hired by the Departments of HHS and Labor to enforce the mandates contained in PARCA?
- What annual Federal appropriations would be required to maintain this staffing level?
- See Chapter Two.

(3) **New Federal Regulations:**
- How many new Federal regulations would have to be promulgated in order for PARCA to become operational?
- See Chapter Three.

(4) **New Federal Litigation -- New Causes of Action:**
- How many new Federal causes of action would be created by PARCA?
- Who would the potential plaintiffs and defendants be?
- What would the impact of this new litigation be on the healthcare delivery system?
- See Chapter Four.
New State Litigation -- Malpractice and Other State-Law Liability Claims:

- How would PARCA increase the exposure of employers, insurers and managed care entities to existing malpractice lawsuits?
- To what new malpractice and other State law liability claims would these "health care issuers" be exposed?
- What would the added costs be to the healthcare delivery system as a result of this new litigation?
- See Chapter Five.

A SUMMARY OF MBS'S CONCLUSIONS

As is set forth in greater detail in the pages that follow, MBS arrived at the following assessment of PARCA impacts:

- **New Regulatory Mandates:** PARCA would impose a total of 207 new regulatory mandates on the public and private sectors, based on the narrow definition of "mandate" found in the Unfunded Mandates Reform Act of 1995. See pages 6-8 and 31-52.

Because State governments would be subject to as many as 91 of these mandates, depending on the extent to which responsibility would be shared between the Federal and State governments (see discussion at page 7), PARCA could result in the imposition of more than 1,000 new mandates on the public sector as a whole.

- **Distribution of New Mandates:** The 207 new mandates would be imposed on the following groups:
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- **Required Annual Appropriations:** Annual appropriations to the Departments of Labor and Health and Human Services ("HHS") would have to be increased by a minimum of $155,294,304.00. See pages 10-14.

- **New Federal Regulations:** The Departments of Labor and HHS would have to jointly promulgate 60 new regulations to implement the 207 new mandates. Each regulation would have to cover a number of different healthcare delivery factual scenarios. Even if all 60 new rulemakings were consolidated into one administrative proceeding, the magnitude of the regulatory effort that would be required in order for PARCA to become operational is immense. See pages 15-21.

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Chapter One
New Regulatory Mandates

MBS was tasked with answering the following questions:

- Using the definition of "mandate" found in the Unfunded Mandates Reform Act of 1995, how many regulatory mandates would be imposed by PARCA?
- Which groups would be directly responsible for compliance with these mandates?
- Who would receive protection from these mandates?

MBS's Analysis

In order to determine the regulatory burden and compliance responsibilities associated with PARCA, MBS performed three exercises:

1. Roster of Mandates: MBS counted the total number of mandates set forth in the bill. The results of this exercise are set forth in Appendix A. MBS counted 207 new mandates, to be distributed among the Federal Government, State governments, private employers offering group coverage, insurers and managed care entities.

Another report counting the requirements contained in PARCA counted "mandates" or "requirements" based on the number of new legal rules contained in the bill, and concluded that PARCA contains upwards of 300 new mandates or requirements (increasing to over 1,000 new mandates or requirements when multiple State and duplicative State and Federal activities are taken into account).

MBS's approach to counting mandates relies the narrow definition of mandate provided by Congress in the Unfunded Mandates Reform Act of 1995: "any provision...that... would impose an enforceable duty." See 2 U.S.C. § 658(5)(A), (7)(A). In other words, MBS counts a provision as a "mandate" if it would result in the imposition of an affirmative duty on a party. Although MBS's approach differs from that of earlier studies, it is significant that other counts arrived at the conclusion that PARCA would impose over 200 new "mandates" or "requirements" on different participants in the healthcare delivery system.
(2) Distribution of Mandates:

-- Health insurance issuers offering network coverage: Health insurance issuers offering network coverage would be responsible for compliance with 108 new mandates. See App. A, ##1-108.

-- Health insurance issuers offering non-network coverage: Health insurance issuers offering non-network coverage would be responsible for compliance with 61 new mandates. See App. A, ##1-61.


-- State governments: States would have the option to enforce PARCA at the State level, or, alternatively to decline enforcement and allow the Federal Government to undertake enforcement. This is because PARCA would be enacted as part of Title XXVII of the Public Health Service Act, which authorizes States to undertake enforcement. If, however, HHS determines that a given State has not substantially enforced one or more PARCA provisions, HHS would have to undertake such enforcement. See App. A, ##200, 201.

Under PARCA, providers would have a strong incentive to demand aggressive enforcement, in light of the fact that a majority of the bill's new mandates are intended to benefit providers. See page 9 below. States do not have the resources to provide for full enforcement of all of the 108 new mandates. (Nor has Congressman Norwood provided for annual appropriations to States to enable them to undertake such enforcement.) Therefore, this study assumes that the enforcement burden will fall jointly on the Departments of HHS and Labor.

1 If, according to proponents of H.R. 1415, States are intended to bear primary enforcement responsibility under PARCA, then the bill is subject to the Unfunded Mandates Reform Act, 2 U.S.C. § 658 et seq., and may be subject to a point of order due to the fact that the costs of burdens on States have not been assessed and reported to Congress. See 2 U.S.C. § 658d(a).

2 To the extent that enforcement burdens are shared by the Federal and State levels, the global costs of enforcement will be greater than the FTE/dollar costs
As this study assesses regulatory burdens based on the assumption of Federal oversight, a rough estimate of the burden that would fall on a given State could be arrived at by multiplying this report's FTE, dollar or litigation estimates by a fraction representing that State's percentage of the U.S. population. (Such an estimate, however, would be an underestimate, because it would not take into account duplicative rulemaking and legislative efforts at the State level, or the loss of economies of scale in pursuing enforcement actions aimed at interstate entities.)

(3) **Who Is Intended to Be Protected?:** In order to determine who would be the primary beneficiaries of the new 108 health insurance issuer mandates, MBS categorized each mandate in terms of whether it is intended to protect patients, providers or health plans. MBS then prepared the chart on page 9, which illustrates the distribution of protections.

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estimated in Chapter Two, due to duplicative, overlapping efforts and the concomitant loss of economies of scale.
Chapter Two
New Federal Hires and Appropriations

MBS was tasked with answering the following questions:

- How many new full-time employees ("FTEs") would have to be hired by the Departments of HHS and Labor to enforce the mandates contained in PARCA?
- What annual Federal appropriations would be required to maintain this staffing level?

**MBS'S ANALYSIS**

Implementation of PARCA would require both HHS and DOL to establish, or substantially increase the staffing of, five offices: (1) Policy Unit; (2) Contract Review Unit; (3) Investigations Unit; (4) Administrative Adjudications Unit; and (5) Appellate Review Unit. Each of these offices within each agency would have to coordinate its activities with its counterpart in the other agency, as well as with State counterparts, to ensure uniform policies and enforcement.

MBS estimates that the following new staffing and corresponding annual appropriations would be required to staff these new Federal offices:

<table>
<thead>
<tr>
<th>New Office</th>
<th>New FTEs</th>
<th>Annual Appropriations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy Units</td>
<td>21</td>
<td>$ 851,928.00</td>
</tr>
<tr>
<td>Contract Review Units</td>
<td>97</td>
<td>$ 3,935,096.00</td>
</tr>
<tr>
<td>Investigations Units</td>
<td>2,966</td>
<td>$120,324,688.00</td>
</tr>
<tr>
<td>Administrative Adjudications Unit</td>
<td>724</td>
<td>$ 29,371,232.00</td>
</tr>
<tr>
<td>Appellate Review Units</td>
<td>20</td>
<td>$ 811,360.00</td>
</tr>
<tr>
<td><strong>TOTAL:</strong></td>
<td><strong>3,828</strong></td>
<td><strong>$155,294,304.00</strong></td>
</tr>
</tbody>
</table>

1. **Policy Units.**

The Policy Units, within both HHS and DOL, would be responsible for: (1) promulgating all of the regulations and standards required under PARCA; (2) responding to specific inquiries based on specific facts through the preparation of advisory opinions or 'no action' letters; (3) preparation of guidance manuals and model contract and policy language; (4) oversight of the Investigation and Enforcement Units to ensure that enforcement is consonant with the Policy Units'
interpretations of the law and broad enforcement strategies and goals; and (5) liaising with Congress, States and the public on all PARCA-related issues.

MBS estimates that a minimum of 21 new FTEs would be required to staff the Policy Units of HHS and DOL. This estimate is based on the experience of HCFA’s Division of Coverage Policy (within the Office of Medicaid Policy, which is within the Medicaid Bureau), which develops rules governing the scope of Medicaid coverage, and is staffed with 21 FTEs.

Based on a Federal employee average compensation rate of $40,568 per year, staffing these offices would require annual appropriations of $851,928.

MBS’s estimate of 21 FTEs is arguably overly conservative in light of the facts that:

• Regulations and guidance will be required to govern virtually all healthcare situations for the entire private insurance market. These new regulations will have to be developed from scratch. Promulgation of 60 new regulations, even if consolidated into one rulemaking proceeding, would require HHS and DOL to gather, make available on a database, consider and comment on literally hundreds of thousands of public comments.

• The proposed rules will be hotly contested in light of the controversial issues concerning the roles of providers and issuers in a number of healthcare delivery situations.

It is worth noting that, as of February 1998, the process of developing a solvency standard for provider service organizations pursuant to the Balanced Budget Act of 1997 has already taken five months, and HHS has not yet settled on the elements of a proposed rule. To cite another example, promulgation of just one standard pursuant to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), that governing mental health parity, took 18 months of HHS effort. This experience illustrates the effort required to promulgate one regulation; yet, under PARCA, HHS and DOL would have to promulgate sixty new standards.

2. Contract Review Units.

The Contract Review Units, within both HHS and DOL, would be responsible for reviewing: (1) all contracts between health professionals/providers and health insurance issuers for compliance with the numerous PARCA provisions governing the professional/provider - health insurance issuer relationship; (2) all health insurance issuer policies, procedures and standards for the credentialing of health professionals and providers; (3) all marketing and informational materials of health insurance
issuers intended for enrollees or potential enrollees; and (4) all contract forms for use with enrollees.

MBS estimates that 97 new FTEs would be required to staff the Contract Review Units. MBS’s estimate is based on the following:

- The State of Illinois utilizes eight FTEs to conduct regulatory review for 41 HMOs in that State. Two of these FTEs, located in the Insurance Department, are engaged in preliminary review of HMO licensing applications; one, located in the Health Department, is responsible for HMO compliance with health statutes and regulations; and five, located in the Insurance Department, are engaged in "final steps" review.

- MBS assumes that two of these FTEs would be needed for ongoing review of health plan - provider agreements, health plan - enrollee agreements, health plan credentialing requirements and health plan marketing and informational materials.

- Under PARCA the number of employers, insurers and managed care entities to be regulated would greatly exceed 2,000 (which is roughly the number of managed care entities in 1997). Therefore, the two FTEs needed in the State of Illinois for initial contract review for 41 HMOs was multiplied by 48.78 to arrive at the staffing level needed for initial contract review for 2,000 entities.

MBS’s estimate is arguably overly conservative, because: (1) MBS has underestimated the number of entities that would be subject to regulation, given the fact that, in addition to managed care entities, employers and insurance companies would also be regulated; and (2) the number of documents of each entity subject to review would be increased.

Based on a Federal employee average compensation rate of $40,568 per year, staffing these offices would require annual appropriations of $3,935,096.00.

3. Investigations Units.

The Investigations Units, within both HHS and DOL, would be responsible for investigating complaints raised by enrollees and providers nationwide concerning noncompliance with PARCA. Additional investigations would be initiated based on information from the Contract Review Units indicating patterns of noncompliance with regard to marketing and informational materials, contracts and policies.

MBS estimates that 2,966 new FTEs would be required to staff the Investigations Units, based on the following:
• In 1993, there were 1,551,000,000 physician/dentist-patient contacts nationwide.\(^3\) Approximately 70.2% of these contacts would be covered by PARCA, because 70.2% of the U.S. population has private health insurance.\(^4\) Therefore, a conservative estimate of the annual number of provider-patient contacts that would be subject to PARCA regulation is 1,088,802,000. (This is actually a highly conservative estimate, because it does not take into account patient contacts with providers who are not physicians or dentists (e.g., nurses, physical therapists, etc.).)

• Assuming a complaint rate of 0.1% (i.e., assuming that for every 1,000 contacts only one complaint is registered alleging a PARCA violation), there would be 1,088,802 complaints per year subject to review and investigation by the relevant regulatory authorities (i.e., HHS, DOL or the States).

• According to HCFA's Office of Benefits Integrity, HCFA's 70 intermediaries investigate approximately 90,000 claims of provider overbilling per year and each intermediary uses 2 to 5 (i.e., an average of 3.5) FTEs to conduct these investigations. These figures indicate that one FTE can investigate approximately 367 complaints per year.

• If one FTE is capable of investigating 367 complaints per year, then 2,966 FTEs would be required to investigate 1,088,802 complaints per year.

Based on a Federal employee average compensation rate of $40,568 per year, staffing these offices would require annual appropriations of $120,324,688.

4. Administrative Adjudications Units.

The Administrative Adjudications Units would be responsible for conducting penalty proceedings, which in Federal administrative practice usually include the following elements: (1) service of process in accordance with the Federal Rules of Civil Procedure; (2) prehearing conferences conducted by administrative law judges ("ALJs") to coordinate stipulations, witnesses, scheduling, discovery issues, potential for settlement, etc.; (3) oversight of document discovery, including motions for sanctions against noncomplying parties; (4) consideration of interlocutory motions, including motions concerning the admissibility of evidence; (5) imposition of sanctions

\(^3\) *Statistical Abstract of the U.S.: 1995*, Table No. 178 at 122.

against parties not complying with the adjudication procedures; (6) conduct of the hearing, which would be open to the public; (7) preparation of a transcript of the hearing, including use of a court reporter; and (8) consideration of post-hearing briefs. See 42 U.S.C. § 1320a-7(a) and 42 C.F.R. Part 1005.

MBS estimates that **724 new FTEs** would be required to staff the Investigations Units, based on the following:

- MBS’s estimate is based on the assumption that only 1/20 of the investigated complaints will proceed to administrative adjudication, i.e., 54,440 penalty proceedings. (This represents only 1/20 of 1/1,000 (i.e., 0.005%) of the annual physician/dentist - patient contacts subject to PARCA regulation.)

- According to the Office of Hearings and Appeals at the Social Security Administration (“SSA”), the SSA employs 7,000 FTEs to conduct 526,000 administrative adjudications per year involving benefits disputes. This means that each FTE is capable of conducting 75.14 adjudications per year.

- Based on the SSA data, 724 FTEs would be required to conduct the 54,440 annual administrative adjudications anticipated under PARCA.

Based on a Federal employee average compensation rate of $40,568 per year, staffing these offices would require annual appropriations of $29,371,232.00.

5. **Appellate Review Units.**

The Appellate Review Units, within both HHS and DOL, would be responsible for considering appeals of the determinations of the Administrative Adjudications Units. In addition, the Appellate Review Units would have to support the Justice Department in the defense of judicial appeals of HHS/DOL determinations.

MBS estimates that **20 new FTEs** would be required to staff the Appellate Review Units, based on the experience of SSA, which maintains a Hearing Counsel consisting of 20 FTEs. These FTEs are responsible for consideration of appeals of ALJ determinations; this 20 FTE figure does not take into account Federal staffing that would be required to defend judicial appeals. Moreover, given the range of novel legal questions that would arise under PARCA, the number of administrative and judicial appeals would arguably be extremely large, so that MBS’s estimate is unduly conservative.

Based on a Federal employee average compensation rate of $40,568 per year, staffing these offices would require annual appropriations of $811,360.
Chapter Three
New Federal Regulations

MBS was tasked with answering the following question:

- How many new Federal regulations would have to be promulgated in order for PARCA to become operational?

MBS's ANALYSIS

Under PARCA, the Departments of HHS and DOL would bear joint responsibility for promulgating and implementing regulations. PARCA § 2(b), which would enact new § 2706(b) of the Public Health Service Act. MBS has identified 60 new regulations that would have to be promulgated in order for PARCA to become operational. In addition, HHS and DOL would have to issue ongoing guidance manuals, including model contract and policy language, and provide ongoing advisory opinions to address the numerous legal and factual questions that would arise.

The 60 new regulations to be promulgated under PARCA are:

ACCESS, NETWORK ADEQUACY AND CONTINUITY OF CARE

(1) Standard for determining what constitutes a "sufficient number, mix and distribution" of health professionals and providers. PARCA § 2771(a)(1).

(2) Standard for determining when the site adequacy and geographic site distribution requirements have been met. PARCA § 2771(a)(1)(B).

(3) Standard for determining whether the "reasonable promptness" of access requirement has been met in multiple health care contexts. PARCA § 2771(a)(1)(C).

(4) Guidelines for compliance with the residential proximity requirement, in light of constantly changing enrollee populations and unique geographical characteristics of each service area. PARCA § 2771(a)(1)(D).

(5) Guidelines for compliance with the obligation to take into account diverse enrollee needs in achieving access. PARCA § 2771(a)(1)(E)(i).

(6) Guidelines for compliance with the adequate continuity-of-care
requirement. PARCA § 2771(a)(1)(E)(ii).

(7) Standard governing the access obligations of HIIs with respect to underserved and rural populations. PARCA § 2771(a)(1).

(8) Regulation setting forth what situations call for the provision of specified kinds of specialized treatment expertise. PARCA § 2771(c)(1) and (2).

(9) Guidelines for determining the range of circumstances under which a change of health professional or provider might disrupt the continuity of care for an enrollee. PARCA § 2772(c)(4).

EMERGENCY CARE AND URGENT CARE SERVICES AND REIMBURSEMENT

(10) Guidelines to enable HIIs to determine whether the "prudent layperson" standard has been met with respect to emergency care services provided without prior authorization. The guidelines would have to enable utilization reviewers, providers and other decisionmakers to distinguish: (i) genuine emergency situations and nonemergency situations which nevertheless would appear to be emergencies to a "prudent layperson." PARCA § 2771(b)(2)(A).

(11) Regulation setting forth what situations call for the provision of "urgent care services." PARCA § 2771(b)(2)(C).

ENROLLEE RIGHTS; NONDISCRIMINATION AGAINST ENROLLEES

(12) Standard setting forth what HIIs must do to comply with the enrollee selection-of-provider and change-of-provider requirements. PARCA § 2772(a)(1).

(13) Standard for determining when a point-of-service option premium is "fair and reasonable" when State requirements are in conflict. PARCA § 2772(b)(2).

(14) Standards for ensuring nondiscrimination against enrollees. PARCA § 2773(a).

(15) Regulation identifying "individually identifiable information" subject PARCA’s confidentiality requirements. PARCA § 2779(a)(2).
Rights of Health Professionals and Providers;
Nondiscrimination Against Health Professionals and Providers

(16) Guidelines setting forth situations, including provider reimbursement scenarios, in which an HII will be deemed to have violated the prohibition against directly or indirectly inducing reductions or limits of medically necessary services. PARCA § 2771(d)(1).

(17) Regulatory definition of the term "substantial financial risk" for purposes of the prohibition against provider incentive plans. PARCA § 2771(d)(1)(B).

(18) Requirements for stop-loss protection to be provided by an HII to health professionals or providers to compensate for the financial risk associated with non-provided services. PARCA § 2771(d)(1)(B).

(19) Guidelines for the reimbursement of non-network professionals and providers for emergency care services, urgent care services and services provided outside the service area, including guidelines for balance billing. PARCA § 2772(b)(3).

(20) Standards for ensuring nondiscrimination against health professionals and providers. PARCA § 2773(b).

(21) Guidelines setting forth multiple situations in which the provider-patient communications provisions will be deemed to have been violated. PARCA § 2774(a) and (c)(1).

(22) Standard for compliance with the requirement that health professionals and providers be integrated into the HII's utilization review process. PARCA § 2776(a)(1).

(23) Regulation establishing procedures for adoption and implementation by HIIs for review of adverse determinations concerning network participation, including denial, suspension and revocation of credentials. PARCA § 2777(a)(1).

(24) Regulation establishing procedures for adoption and implementation by HIIs for the credentialing of health professionals and providers. PARCA § 2777(a)(1).

(25) Regulation setting forth permitted objective quality standards for selecting participating health professionals and providers. PARCA § 2777(a)(4).
(26) Regulation setting forth permitted economic considerations for use in selecting health professionals and providers. PARCA § 2777(a)(6).

(27) Regulation setting forth permitted methodologies for the uniform and objective adjustment by HII s of health professional and provider economic profiles. PARCA § 2777(a)(7).

INFORMATIONAL AND MARKETING MATERIALS

(28) Regulation setting forth the specific categories of services into which information must be organized in HII informational and marketing materials. PARCA § 2778(a)(1)(A).

(29) Regulation setting forth the specific categories of health professionals and providers into which information must be organized in HII informational and marketing materials. PARCA § 2778(a)(1)(B).

(30) Regulation setting forth a uniform methodology for calculating the percentage of the premium charged by the plan that is set aside for administration and marketing. PARCA § 2778(a)(2).

(31) Regulation setting forth a uniform methodology for calculating the percentage of the premium charged by the plan that is expended directly on patient care. PARCA § 2778(a)(3).

(32) Regulation setting forth a uniform format for the disclosure to enrollees and prospective enrollees of information about the ratio of enrollees to participating health professionals and providers by type of professional and provider. PARCA § 2778(a)(5).

(33) Regulation setting forth a uniform format for the disclosure to enrollees and prospective enrollees of information about the plan's expenditures and utilization per enrollee by type of health professional and provider. PARCA § 2778(a)(6).

(34) Regulation setting forth a uniform format for the disclosure to enrollees and prospective enrollees of information about enrollee financial obligations for premiums, copayments and deductibles, including obligations for services provided by non-participating health professionals and providers and services provided to enrollees outside the service area. PARCA § 2778(a)(7).

(35) Regulation setting forth a uniform format for the disclosure to enrollees and prospective enrollees of information about financial/non-financial
arrangements/incentives that could limit the items and services furnished to an enrollee, restrict referral or treatment options, or negatively affect the fiduciary responsibility of a health professional or provider to an enrollee. PARCA § 2778(a)(9) and (10).

(36) Regulation setting forth a uniform format for the disclosure to enrollees and prospective enrollees of information about quality indicators for the HII and participating health professionals and providers, including performance measures such as appropriate referrals and prevention of secondary complications following treatment. PARCA § 2778(a)(11).

(37) Regulation establishing a uniform procedure for the gathering and disclosing of information about the percentage of utilization review determinations made by the HII that disagree with the judgment of the treating health professional or provider and the percentage of such determinations that are reversed on appeal. PARCA § 2778(a)(13).

(38) Standard governing the styles and sizes of type to be used in informational and marketing materials. PARCA § 2778(b)(1).

(39) Standard governing the accessibility and comprehensibility of informational and marketing materials. PARCA § 2778(b)(2).

(40) Standard governing the placement and positioning of information in health plan informational and marketing materials. PARCA § 2778(b)(2).

**UTILIZATION REVIEW**

(41) Guidelines setting forth methods for disclosing utilization review screening and other criteria consistent with protection of the HII's proprietary information. PARCA § 2776(a)(2).

(42) Ongoing promulgation of standards setting forth specific new medical developments to be taken into account in making utilization review determinations. PARCA § 2776(a)(3).

(43) Standard for determining what information about individuals conducting utilization review can be released, and under what circumstances, as well as what "reasonable safeguards" must be implemented by the HII. PARCA § 2776(a)(5).

(44) Guidelines setting forth specific situations in which an HII will be deemed to have compensated individuals conducting utilization review
for denials of payment or coverage. PARCA § 2776(a)(6).

(45) Standard setting forth language to be included in utilization review determination notices concerning the right to appeal. PARCA § 2776(a)(9).

(46) Standard for determining when information provided to an HII for utilization review can be deemed sufficiently false so as to enable the HII to reverse its determination. PARCA § 2776(a)(10).

(47) Regulation establishing procedures for adoption and implementation by HIIs for review of adverse utilization review and adverse care determinations. PARCA § 2776(b)(1) and (2).

DEFINITIONAL REGULATIONS

(48) Regulatory definition of the term "enrollee," reflecting the fact that the PARCA definition differs from that used in the Medicare statute. The regulation would have to address conflicts or inconsistencies stemming from the two varying statutory definitions. PARCA § 2770(b)(1).

(49) Regulatory definition of the term "health professional," reflecting the fact that the PARCA definition differs from that used in the Medicare statute. The regulation would have to address conflicts or inconsistencies stemming from the two varying statutory definitions. PARCA § 2770(b)(2).

(50) Regulatory definition of the term "network," reflecting the fact that the PARCA definition differs from that used in HIPAA. The regulation would have to address conflicts or inconsistencies stemming from the two varying statutory definitions. PARCA § 2770(b)(3).

(51) Regulatory definition of the term "network coverage," reflecting the fact that the PARCA definition differs from that used in HIPAA. The regulation would have to address conflicts or inconsistencies stemming from the two varying statutory definitions. PARCA § 2770(b)(4).

(52) Regulatory definition of the term "participating." PARCA § 2770(b)(5).

(53) Regulatory definition of the term "prior authorization," taking into account varying definitions under State laws. PARCA § 2770(b)(6).

(54) Regulatory definition of the term "provider," taking into account varying definitions under State laws. PARCA § 2770(b)(7).
(55) Regulatory definition of the term "service area," reflecting the fact that the PARCA definition differs from that used in the Medicare statute. The regulation would have to address conflicts or inconsistencies stemming from the two varying statutory definitions. PARCA § 2770(b)(8).

(56) Regulatory definition of the term "utilization review." PARCA § 2770(b)(9).

(57) Regulatory definition of the term "notice," taking into account PARCA's new enrollee notification requirements. PARCA § 2770(a).

(58) Regulatory definition of the term "adequate arrangements" to ensure access, for use by self-insured plans. PARCA § 2771(a)(1).

QUALITY IMPROVEMENT PROGRAMS

(59) Regulation identifying accreditation body standards compliance with which will constitute compliance with PARCA's quality improvement program requirements. PARCA § 2780(a)(1).

(60) Regulation establishing quality improvement program requirements in addition to existing private accreditation body requirements. PARCA § 2780(a)(1).
Chapter Four
New Federal Litigation -- New Causes of Action

MBS was tasked with answering the following questions:

- How many new Federal causes of action would be created by PARCA?
- Who would the potential plaintiffs and defendants be?
- What would the impact of this new litigation be on the healthcare delivery system?

MBS'S ANALYSIS

NEW CAUSES OF ACTION; POTENTIAL PLAINTIFFS

MBS has identified the following 33 new Federal causes of action against health insurance issuers, which would be prosecuted by enrollees and health professionals and providers:

1. Failure to maintain "adequate arrangements" to ensure access to the full package of items and services. PARCA § 2771(a)(1).

2. Failure to provide continuity of care. PARCA § 2771(a)(1)(E)(ii).

3. Failure to provide emergency or urgent services coverage. PARCA § 2771(b).

4. Failure to reimburse a health professional or provider for emergency or urgent care services. PARCA § 2771(b).

5. Discrimination against an enrollee on the basis of: (a) race; (b) national origin; (c) gender; (d) language; (e) socio-economic status; (f) age; (g) disability; (h) health status; or (h) anticipated need for services. PARCA § 2773(a).

6. Discrimination against a health professional or provider on the basis of license or certification. PARCA § 2773(c).

7. Imposition of contractual terms, or other health insurance issuer ("HII") practices, that prohibit or restrict the health professional or provider from engaging in medical communications with his or her patient.
PARCA § 2774(a) and (c)(1).

(8) Challenges to utilization review programs or individual utilization review determinations on the grounds that health professionals and providers were not given adequate input, or on the grounds that professional/provider suggestions were not adopted. PARCA § 2776(a)(1).

(9) Challenges to utilization review programs or individual utilization review determinations on the grounds that the HII's screening criteria, weighting elements and computer algorithms are inappropriate. PARCA § 2776(a)(2).

(10) Broad-based, and individual, challenges to an HII's utilization review determination results on the grounds that the HII's utilization review standards are not uniformly applied. PARCA § 2776(a)(3).

(11) Challenges to individual, adverse utilization review determinations on the grounds that the determinations do not take into account the latest, state-of-the-art medical advances. PARCA § 2776(a)(3).

(12) Challenges to individual, adverse utilization review determinations based on the involvement of non-licensed HII personnel in the determination process. PARCA § 2776(a)(4).

(13) Lawsuits to compel disclosure of the names and credentials of utilization review personnel. Counter-motions by utilization review personnel to prohibit the disclosure of confidential or unnecessary personal information. PARCA § 2776(a)(5).

(14) Lawsuits to compel disclosure of HII practices to determine whether the HII is compensating individuals conducting utilization review of denials of payment or coverage. PARCA § 2776(a)(6).

(15) Judicial appeals of the appellate decisions of HIIs concerning utilization review. PARCA § 2776(a)(9).

(16) Challenges to HII reversals of initial, favorable utilization review determinations, turning on the question of whether false information was provided to the HII. PARCA § 2776(a)(10).

(17) Broad-based challenges to the informational materials, disclosure and marketing practices of HIIs. PARCA § 2778(a).
(18) Broad-based challenges to HII ratemaking practices based on percentages of premium charges allocable to patient care versus HII administration. PARCA § 2778(a)(4).

(19) Breach of State law confidentiality restrictions. PARCA § 2779(a)(1).

(20) Broad-based challenges to the HII's quality improvement program. PARCA § 2780(a)(2).

(21) Defamation actions by health professionals and providers stemming from the HII's dissemination of assessments of professional/provider performance to health care purchasers and others. PARCA § 2780(b)(1).

(22) Failure of the HII to provider specialized treatment services. PARCA § 2771(c)(1).

(23) Damages for injuries stemming from malpractice induced by payments or other incentives to health professionals or providers as an inducement to reduce or limit medically necessary services. PARCA § 2771(d)(1)(A).

(24) Failure to allow a specific enrollee to select the specific health professional or provider of his or her choice (and to change that selection at will). PARCA § 2772(a).

(25) Challenges to the premium rates for point-of-service options. PARCA § 2772(b)(2).

(26) Challenges by non-network professionals and providers to their reimbursement rates on the grounds that such rates are less than the rates paid to network professionals and providers. PARCA § 2772(b)(3).

(27) Challenges by enrollees with special health care needs or chronic conditions to the coordination of care and cost control processes of the HII. PARCA § 2772(c).

(28) Discrimination against a health professional or provider on the basis of: (a) race; (b) national origin; (c) gender; (d) age; (e) disability; or (f) lack of affiliation with, or admitting privileges at, a hospital. PARCA § 2773(b).

(29) Failure to consider the input of enrollees regarding the HII's medical policies, utilization review criteria and procedures, quality and credentialing criteria and medical management procedures. PARCA § 2775.
(30) Failure to comply with the annual process for credentialing of health professionals and providers within the service area, including challenges to the credentialing criteria. PARCA § 2777(a).

(31) Challenges to termination of health professional or provider network participation turning on the question of whether "cause" was present. PARCA § 2777(a)(11).

(32) Judicial appeals of the determinations of health professional/provider review boards established by HII s, including appeals of HII interlocutory determinations. PARCA § 2777(a)(12).

(33) Challenges to adverse actions against health professionals or providers on the grounds that the procedural requirements of section 2777(a)(12) were not fully met. PARCA § 2777(a)(12).

IMPACT ON THE HEALTHCARE DELIVERY SYSTEM

The judicial impact of these new causes of action would not be directly proportionate to the administrative enforcement burdens identified in Chapter Two for the reasons that follow. These new Federal-law causes of action would be independent of administrative investigations and enforcement proceedings, because: (1) aggrieved enrollees and providers not satisfied with the determinations of administrative tribunals would seek judicial review; and (2) plaintiffs would not be able to obtain all of the desired remedies at the administrative level. The interrelationship between the administrative and judicial processes would involve the following considerations:

-- Where an enrollee or provider perceives that time is of the essence, he or she would go immediately to court to seek injunctive relief to prevent irreparable harm. In this situation, the courts would hold that the plaintiff could not afford to wait for the administrative investigation and adjudication process to reach its conclusion.

-- Where the administrative tribunal rules in favor of the complainant, the complainant would in many cases still have to go to court to obtain kinds of relief not available at the administrative level (e.g., damages for financial loss, punitive damages, etc.).

-- Where the administrative tribunal rules against the complainant, the complainant would in many instances appeal the decision in the Federal district court.
There would be substantial appellate-level litigation, as different Federal circuit courts develop conflicting legal rules for myriad factual scenarios that will be the subject of disputes under PARCA.

PARCA would encourage new class action litigation and aggressive plaintiffs law firms would actively promote such litigation. For example, all enrollees in a given health plan who were denied a given medical procedure would constitute a class. Similarly, all physicians in a given service area would constitute a class, and, as such, could sue a plan to challenge the plan's economic profiling criteria.

Assuming that: (1) 3% of providers (active physicians, dentists and nurses) -- including those participating in a given plan as well as those who are disgruntled by their exclusion from network participation -- challenge health plans regarding credentialing processes and methodologies, specific credentialing determinations, reimbursement determinations or based on any other grounds set forth at pages 22-25 above; and (2) 0.015% of provider-patient contacts result in lawsuits against health plans, the result would be: (1) 84,624 new provider lawsuits filed per year; and (2) 163,320 new enrollee lawsuits filed per year against health plans.

The provider figure is probably substantially underestimated, because entire categories of health professionals, such as physical therapists, are not included in the base figure.

This translates into a minimum total of 247,944 new lawsuits per year, not including lawsuits alleging State-law liability, such as malpractice. See Chapter Five. The costs of this litigation explosion would be borne by employers and plan beneficiaries, and would take the form of higher premiums and reduced or eliminated coverage.

Deleterious collateral effects of the litigation explosion that would result from enactment of PARCA would include the following:

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5  This 0.015% figure is drawn from the discussion at page 13 above, where it was posited that 0.1% of the annual provider-patient contacts would result in the filing of administrative complaints. It was then posited that 15% of these administrative complaints would result in lawsuits, i.e., 0.015% of the original annual provider-patient contacts, or 163,320 lawsuits.

6  This figure is based on a physician/dentist/nurse population of 2,820,800. See Statistical Abstract of the U.S.: 1996, Table Nos. 179 and 180.
• The threat of often-spurious litigation would enable organized groups of providers to effectively extort changes in the policies of health plans that would substantially increase costs (i.e., premiums) but would not necessarily result in better healthcare. For example, a health plan could be obligated to lower its credentialing standards for network participation in order to avoid liability for "provider discrimination." This would result in lower quality of care for enrollees.

• Both providers and enrollees would have a tremendous incentive to employ the leverage provided by the new PARCA causes of action in any disputes, major or minor, with health plans. This would not only encourage the filing of lawsuits, but would also compel health plans to make inappropriate and costly process/policy changes and credentialing decisions to avoid litigation.

• Health insurance issuers would be required to engage in "defensive medicine" practices to avoid liability under the new causes of action. This would result in higher premiums without any corresponding increase in the quality of care.

• Day-to-day health plan operations would be significantly impeded, as plans would be required to spend staff time responding to the demands of litigation. Employers and health plans would have to spend significant professional and administrative time producing documents and testifying at depositions, mediation proceedings and trials. Insurance or HMO personnel and participating providers who are forced to travel from home offices or medical facilities in order to be deposed in distant locations are not able to provide services to health plans or their enrollees.
Chapter Five
New State Litigation -- Malpractice and Other Liability Claims

MBS was tasked with assessing the following questions:

- How would PARCA increase the exposure of employers, insurers and managed care entities to existing malpractice lawsuits?

- To what new malpractice and other State-law liability claims would these "health care issuers" be exposed?

- What would the added costs be to the healthcare delivery system as a result of this new litigation?

MBS's Analysis

PARCA would create three new categories of State-law liability exposure (including, but not limited to, malpractice exposure) that would have to be passed onto employers and enrollees through higher premiums:

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Category No. 1: Health insurance issuers would be brought in as co-defendants (by either the plaintiffs or the original defendants) in existing malpractice lawsuits. The original defendant (e.g., physician) could join the health insurance issuer by alleging that conduct of the HII caused the physician to commit the acts or omissions that resulted in the alleged malpractice.

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Category No. 2: Health insurance issuers would be sued directly by enrollees on the theory that the HII's appropriateness determination (i.e., the decision of the HII's utilization review staff person that approval of a covered item or service should be denied in a specific instance based on all of the surrounding medical circumstances) caused injury to the enrollee.

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Category No. 3: Health insurance issuers would be sued directly by enrollees on the theory that the HII's coverage determination (i.e., the determination of the health insurance issuer's utilization review staff person that a requested item or service is not covered by the policy) resulted in injury to the enrollee.

Each of these three new Categories would result in strong financial incentives for potential plaintiffs to file lawsuits, because employers, insurers and managed care
entities would become "deep pockets."

In assessing the extent of State-law liability exposure, it is important to emphasize that this new exposure would not be limited to medical malpractice causes of action. H.R. 1415's companion bill, H.R. 2960, clarifies that managed care entities would be subject to any State law causes of action for any of the following:

- Personal injury, based on any legal theory recognized by State law (i.e., not limited to traditional medical malpractice);
- Financial injury, based on any legal theory recognized by State law; and
- Wrongful death, based on any legal theory recognized by State law.

During the 1984 calendar year, 73,500 medical malpractice lawsuits were filed in the U.S. 57% of medical malpractice lawsuits are closed without payment to the plaintiff; the other 43% result in payment.\(^7\) The average malpractice indemnity award as of 1995 had risen to $398,426.\(^8\) The defense of meritless claims cost $737,000,000 during that same year.\(^9\)

It would be impossible to determine the exact number of new malpractice and other State-law liability suits that would be filed against employers, insurers and managed care entities, because the new legal exposures represented by malpractice and other State-law liability Categories 1-3 (set forth on page 28 above) are without precedent. Therefore, to provide a general indication of the immensity of State-law liability costs associated with PARCA, MBS has posited that new, State-law liability claims against ERISA plans subject to PARCA would be equivalent to 20% of the current medical malpractice litigation load. Such an increase in litigation would impose a minimum cost of $986,879,368.00 on the healthcare delivery system, comprising the following two main elements:

- $147,400,000.00 per year to defend meritless claims; and
- $839,479,368.00 per year in damages payouts, based on the following assumptions:


\(^9\) Id.
With a 20% increase in the number of lawsuits involving health insurance issuers, health insurance issuers would be named as defendants in 14,700 lawsuits per year;

6,321 of these lawsuits (i.e., 43%) would result in damages payouts;

The health insurance issuer would be required to pay one third of the average damages payout of $398,426, i.e., $132,808.

This $986,879,368.00 increase in the annual cost of healthcare delivery would be borne by employers and enrollees in ERISA plans.
MANDATES APPLICABLE TO ALL HEALTH INSURANCE ISSUERS ("HIIs") AND HEALTH PLANS, BOTH NETWORK AND NON-NETWORK

1. Establish and maintain "adequate arrangements" to ensure access, as defined by each State (in the case of insured plans) and by the Department of Labor (in the case of self-insured plans). PARCA § 2771(a)(1).

2. Comply with the "sufficient number, mix and distribution of health professionals and providers" requirements, as elaborated in applicable Federal and State regulatory standards. PARCA § 2771(a)(1).

3. Ensure that covered items and services are available and accessible to each enrollee. This would require the HII to monitor compliance with the access requirements on a nonstop basis as new enrollees with residences in different locations join the HII. PARCA § 2771(a)(1).

4. Ensure that the access standards are met throughout the service area. PARCA § 2771(a)(1)(A).

5. Comply with the "variety of sites" requirements, as elaborated in applicable Federal and State regulatory standards concerning the number and geographic distribution of sites required to meet the "variety" requirement. PARCA § 2771(a)(1)(B).

6. Ensure compliance with the access requirements "with reasonable promptness." PARCA § 2771(a)(1)(C).

7. Ensure access within reasonable proximity to residences and workplaces of enrollees. The HII would have to monitor compliance with the residential/workplace proximity requirement on a nonstop basis as new enrollees with residences and workplaces in different locations join the plan. PARCA § 2771(a)(1)(D).

8. Ensure access in a manner to account for the diverse needs of enrollees. The HII would have to monitor compliance with this "diverse needs" requirement on a nonstop basis to take into account: (i) new enrollees; and (ii) changing needs of existing enrollees. PARCA § 2771(a)(1)(E)(i).

9. Ensure, through the development and implementation of appropriate policies
and procedures, that access is provided in a manner that reasonably assures continuity of care. PARCA § 2771(a)(1)(E)(ii).

10. To the extent that the plan serves populations in medically underserved or rural areas, comply with special access rules applicable to rural and underserved areas. PARCA § 2771(a)(1).

11. Ensure the availability and accessibility of medically or clinically necessary emergency care and urgent care services within the service area 24 hours per day, seven days per week. PARCA § 2771(b)(1)(A).

12. Ensure that no prior authorization is required for care provided in an emergency department to an enrollee with symptoms that would reasonably suggest to a "prudent layperson" an emergency condition. This requirement would apply regardless of whether the health professional or hospital had a contractual or other arrangement with the HII. PARCA § 2771(b)(1)(B).

13. Cover, and make reasonable payments for: (i) emergency services; (ii) nonemergency services covered by the "prudent layperson" rule; (iii) screening examinations and other services ancillary to emergency treatment; and (iv) urgent care services (regardless of whether the health professional or provider furnishing such services has a contractual or other arrangement with the HII). PARCA § 2771(b)(1)(C).

14. Make prior authorization determinations for: (i) nonemergency care services subject to coverage and reimbursement under the "prudent layperson" standard (within 24 hours of the request for authorization); and (ii) urgent care services (within 30 minutes of the request for authorization). PARCA §§ 2771(b)(1)(D) and 2776(a)(8).

15. Ensure that the HII's contractual arrangements do not contain provisions that could result in discrimination against any individual on the basis of race, national origin, gender, language, socio-economic status, age, disability, health status or anticipated need for services. PARCA § 2773(a).

16. Ensure, through appropriate policies and procedures, that none of the HII's activities result in discrimination against any individual on the basis of race, national origin, gender, language, socio-economic status, age, disability, health status or anticipated need for services. PARCA § 2773(a).

17. Ensure, through appropriate policies and procedures, that the HII does not discriminate in participation, reimbursement, or indemnification against a health care professional, who is acting within the scope of his or her license or
certification under applicable State law, solely on the basis of such license or certification. PARCA § 2773(c).

18. Ensure, through drafting appropriate contractual terms and entering into appropriate contractual arrangements, that no health professional is prohibited or restricted from engaging in medical communications with his or her patient. PARCA § 2774(a) and (c)(1).

19. Involve participating health professionals and providers in the development of the HII's utilization review program (including the screening criteria to be used in the program). PARCA § 2776(a)(1).

20. Make the HII's screening criteria, weighting elements and computer algorithms used in utilization review available upon request to affected health professionals, providers and enrollees. PARCA § 2776(a)(2).

21. Develop, and make available to affected health professionals, providers and enrollees upon request, descriptions of the HII's screening criteria, weighting elements and computer algorithms used in the utilization review program. PARCA § 2776(a)(2).

22. Ensure, through the development and implementation of appropriate guidelines and procedures, that the HII's release of information pertaining to its screening criteria, weighting elements and computer algorithms is consistent with the protection of the HII's proprietary information, in accordance with applicable HHS/DOL regulatory guidance. PARCA § 2776(a)(2).

23. Ensure, through the development and implementation of appropriate policies and procedures, that utilization review criteria are uniformly applied. PARCA § 2776(a)(3).

24. Ensure that the HII's utilization review criteria are based on sound scientific principles. PARCA § 2776(a)(3).

25. Ensure, in developing the HII's utilization review criteria, that the most recent medical evidence is taken into account. Periodically review and update the utilization review criteria to take into account new medical developments. PARCA § 2776(a)(3).

26. Ensure that all utilization review determinations are made by licensed, accredited or certified health professionals. PARCA § 2776(a)(4).

27. Ensure that utilization review determinations for services requiring specialized
training for their delivery are made by health professionals with equivalent specialized training or expertise. PARCA § 2776(a)(4).

28. Disclose to health professionals and providers, upon request, the names and credentials of individuals conducting utilization review. PARCA § 2776(a)(5).

29. Establish "reasonable safeguards" for use by the HII in releasing the names and credentials of individuals conducting utilization review. PARCA § 2776(a)(5).

30. Ensure, through the development and implementation of appropriate guidelines and procedures, that the HII does not compensate individuals conducting utilization review for denials of payment or coverage. PARCA § 2776(a)(6).

31. Include, in each notice of each utilization determination, an explanation of the basis of the determination and the right to appeal. PARCA § 2776(a)(9).

32. Ensure, through the establishment and implementation of appropriate guidelines and procedures, that an initial favorable utilization determination cannot be overturned, even if the determination was inappropriate, unless the initial determination was based on false information provided to the HII. PARCA § 2776(a)(10).

33. Ensure that the HII provides "timely access" (in accordance with the varying regulatory definitions of that term in each of the States in which the HII operates) to its utilization review personnel. PARCA § 2776(a)(11).

34. Provide notice of an initial determination on payment of a claim within 30 days after the date the claim is submitted for the item or service, including in the notice an explanation of the reasons for the determination and the right to an immediate appeal. PARCA § 2776(a)(12).

35. Establish and maintain an appeals process for the review of adverse care determinations that assures that: (i) adverse urgent care determinations are reviewed within one hour of the request for review; (ii) adverse non-urgent care determinations are reviewed within 24 hours of the request for review; and (iii) adverse payment determinations are reviewed within 30 days of the request for review. PARCA § 2776(b)(1) and (2).

36. Ensure, through the establishment and implementation of appropriate guidelines and procedures, that reviews of initial adverse utilization determinations are made by appropriate clinical peer professionals in the same or similar specialties as would typically provide the items or services involved.
PARCA § 2776(b)(3).

37. Ensure, through the establishment and implementation of appropriate guidelines and procedures, that the clinical peer professionals who review initial adverse utilization determinations or enrollee access complaints are not involved in the operation of the HII or in the making of the determination or policy being appealed. PARCA § 2776(b)(4).

38. Provide enrollees and prospective enrollees with information about HII coverage, benefits and exclusions organized by categories of services. PARCA § 2778(a)(1)(A).

39. Provide enrollees and prospective enrollees with information about plan coverage, benefits and exclusions organized by type of health professional or provider. PARCA § 2778(a)(1)(B).

40. Provide enrollees and prospective enrollees with lists of specific services available under the plan, including experimental treatments. PARCA § 2778(a)(1)(C).

41. Disclose to enrollees and prospective enrollees the percentage of the premium charged by the plan that is set aside for administration and marketing. PARCA § 2778(a)(2).

42. Disclose to enrollees and prospective enrollees the percentage of the premium charged by the plan that is expended directly on patient care. PARCA § 2778(a)(3).

43. Disclose to enrollees and prospective enrollees information about the number, mix and distribution of participating health professionals and providers. PARCA § 2778(a)(4).

44. Disclose to enrollees and prospective enrollees information about the ratio of enrollees to participating health professionals and providers by category and type of professional and provider. PARCA § 2778(a)(5).

45. Disclose to enrollees and prospective enrollees information about the plan's expenditures and utilization per enrollee by category and type of health professional and provider. PARCA § 2778(a)(6).

46. Disclose to enrollees and prospective enrollees information about enrollee financial obligations of both the enrollee and the HII for premiums, copayments and deductibles, and established aggregate maximums on out-of-pocket costs for all items and services (including those provided by non-
participating health professionals and providers and those provided to enrollees outside the service area). PARCA § 2778(a)(7).

47. Provide enrollees and prospective enrollees with information about the plan’s utilization review requirements, including prior authorization review, concurrent review, post-service review, post-payment review and any other procedures that could lead to denial of coverage or payment. PARCA § 2778(a)(8).

48. Provide enrollees and prospective enrollees with information about financial arrangements and incentives that could limit the items and services furnished to an enrollee, restrict referral or treatment options, or negatively affect the fiduciary responsibility of a health professional or provider to an enrollee. PARCA § 2778(a)(9).

49. Provide enrollees and prospective enrollees with information about nonfinancial incentives for health professionals and providers to deny or limit needed items or services. PARCA § 2778(a)(10).

50. Provide enrollees and prospective enrollees with information about quality indicators for the HII and participating health professionals and providers, including performance measures such as appropriate referrals and prevention of secondary complications following treatment. PARCA § 2778(a)(11).

51. Provide enrollees and prospective enrollees with information about grievance procedures and appeals rights under the coverage, and summary information about the number and disposition of grievances and appeals in the most recent period for which complete and accurate information is available. PARCA § 2778(a)(12).

52. Provide enrollees and prospective enrollees with information about the percentage of utilization review determinations made by the HII that disagree with the judgment of the treating health professional or provider and the percentage of such determinations that are reversed on appeal. PARCA § 2778(a)(13).

53. Comply with HHS/DOL standards pertaining to the styles and sizes of type to be used in informational and marketing materials. PARCA § 2778(b)(1).

54. Comply with HHS/DOL standards for informational and marketing materials aimed at ensuring accessibility and comprehensibility. PARCA § 2778(b)(2).

55. Comply with HHS/DOL standards regarding the placement and positioning of information in health plan informational and marketing materials. PARCA §
Establish explicit mechanisms and procedures to ensure compliance with Federal and State laws designed to protect the confidentiality of individually identifiable information pertaining to enrollees, health professionals and providers. PARCA § 2779(a)(1).

Ensure that the HII's quality improvement program systematically and continually assesses and improves enrollee health status, patient outcomes, processes of care and enrollee satisfaction. PARCA § 2780(a)(1).

Ensure that the HII's quality improvement program systematically and continually assesses and improves the HII's administrative and funding capacities of the HII to support and emphasize preventive care, utilization, access and availability, cost effectiveness, acceptable treatment modalities, specialist referrals, the peer review process and the efficiency of the administrative process. PARCA § 2780(a)(2).

As part of the quality improvement program, assess the performance of the HII and its participating health professionals and providers and report the assessment results to purchasers, participating health professionals and providers, and administrative personnel. PARCA § 2780(b)(1).

As part of the quality improvement program, demonstrate measurable improvements in clinical outcomes and plan performance measured by identified criteria. PARCA § 2780(b)(2).

As part of the quality improvement program, analyze quality assessment data to determine specific interactions in the delivery system (both the design and funding of the health insurance coverage and the clinical provision of care) that have an adverse impact on the quality of care. PARCA § 2780(b)(3).
MANDATES APPLICABLE TO NETWORK HEALTH INSURANCE ISSUERS AND NETWORK PLANS

62. Demonstrate to HHS or DOL that enrollees have access to specialized treatment expertise when such treatment is medically or clinically indicated in the professional judgment of the treating health professional, in consultation with the enrollee. PARCA § 2771(c)(1).

63. Ensure that no specific payment is made directly or indirectly under the plan to a health professional or provider as an inducement to reduce or limit medically necessary services to a specific enrollee. PARCA § 2771(d)(1)(A).

64. Determine whether the HII places health professionals or providers at substantial financial risk for services not provided by the professional or provider. If such is the case, provide stop-loss protection based on standards developed by HHS and DOL. PARCA § 2771(d)(1)(B)(i).

65. If the HII places health professionals or providers at substantial financial risk for services not provided by the professional or provider, conduct periodic surveys of enrollees and disenrollees regarding satisfaction with health care quality. PARCA § 2771(d)(1)(B)(ii).

66. Provide descriptive information to HHS/DOL sufficient to permit HHS/DOL to determine whether the HII is in compliance with the prohibition against incentive plans reducing or limiting medically necessary services. PARCA § 2771(d)(1)(C).

67. Ensure, through appropriate policies and procedures, that each enrollee is permitted to select the personal health professional of his or her choice from among the participating professionals. PARCA § 2772(a)(1).

68. Ensure, through appropriate policies and procedures, that each enrollee is permitted to change his or her selection of personal health professionals as appropriate. PARCA § 2772(a)(2).

69. Offer a point-of-service option to network enrollees. PARCA § 2772(b)(1).

70. Ensure that the premiums for point-of-service options comply with the "fair and reasonable" standards established by each State in which the HII offers coverage. PARCA § 2772(b)(2).

71. Ensure that the reimbursement rate paid to non-network health professionals and providers are not less than those applied to network professionals and providers. PARCA § 2772(b)(3).
72. Institute accounting, bookkeeping and payment procedures for reimbursement of enrollees subject to balance billing by non-network health professionals and providers pursuant to point-of-service options. PARCA § 2772(b)(3).

73. Ensure that the coordination of care or cost control processes established by the HII do not create undue burden, based on applicable State law standards, for enrollees with special health care needs or chronic conditions. PARCA § 2772(c)(1).

74. Ensure direct access to relevant specialists for the continued care of enrollees with special health care needs and chronic conditions when medically or clinically indicated in the judgment of the treating health care professional, in consultation with the enrollee. PARCA § 2772(c)(2).

75. Determine, after consultation with treating health professionals and enrollees with special health care needs or chronic conditions, whether it is medically or clinically necessary to use specialists or care coordinators from interdisciplinary teams to ensure continuity of care for such enrollees. PARCA § 2772(c)(3).

76. Provide for continued coverage of items and services by the original health professional or provider where circumstances (such as change of hospital or dependence on high-technology home medical equipment) indicate that a change of health professional or provider might disrupt the continuity of care for an enrollee. PARCA § 2772(c)(4).

77. Ensure that the HII does not discriminate, in the selection of members of its health professional network, on the basis of race, national origin, gender, age, disability, or the health professional's lack of affiliation with, or admitting privileges at, a hospital. PARCA § 2773(b).

78. Establish network membership terms and conditions that ensure that the HII does not discriminate against health professionals on the basis of race, national origin, gender, age, disability, or the health professional's lack of affiliation with, or admitting privileges at, a hospital. PARCA § 2773(b).

79. Establish mechanisms to consider the recommendations, suggestions and views of enrollees regarding the HII's medical policies, utilization review criteria and procedures, quality and credentialing criteria and medical management procedures. PARCA § 2775.

80. Establish mechanisms to consider the recommendations, suggestions and views of participating health professionals and providers regarding the HII's medical policies, utilization review criteria and procedures, quality and credentialing
criteria and medical management procedures. PARCA § 2775.

81. Allow all health professionals and providers in the HII's service area to apply for participation in the HII's network at least once per year. PARCA § 2777(a)(1).

82. Provide reasonable notice to all health professionals and providers in the HII's service area of the opportunity to apply for network participation and of the period during which applications will be accepted. PARCA § 2777(a)(2).

83. Provide for the review of each application for network participation by a credentialing committee with appropriate representation of the category or type of health professional or provider. PARCA § 2777(a)(3).

84. Ensure, through the establishment and implementation of appropriate guidelines and procedures, that participating health professionals and providers are selected based on objective quality standards. PARCA § 2777(a)(4).

85. Develop objective quality standards for network participation taking into account the suggestions and advice of professional associations, health professionals and providers. PARCA § 2777(a)(4).

86. Make network participation standards available to applicants (health professionals and providers), health plan purchasers and enrollees. PARCA § 2777(a)(5).

87. When economic considerations are taken into account in selecting participating health professionals and providers, use objective criteria. PARCA § 2777(a)(6).

88. When economic considerations are taken into account in selecting participating health professionals and providers, make those criteria available to applicants. PARCA § 2777(a)(6).

89. When economic considerations are taken into account in selecting participating health professionals and providers, adjust the economic profile of each provider to take into account patient characteristics (such as severity of illness) that may result in atypical utilization of services. PARCA § 2777(a)(7).

90. When economic considerations are taken into account in selecting participating health professionals and providers, make the results of individual health professional and provider profiling available to insurance purchasers, enrollees and the health professionals or providers involved. PARCA § 2777(a)(8).
91. Notify each health professional or provider being reviewed for network participation of any "detrimental information" indicating that the applicant fails to meet the HII's standards. PARCA § 2777(a)(9).

92. Offer the health professional or provider with the opportunity to review the detrimental information and to submit corrective information. PARCA § 2777(a)(10).

93. Ensure that the HII does not include in its contracts with participating health professionals and providers any provision permitting the HII to terminate the contract "without cause." PARCA § 2777(a)(11).

94. Establish a due process appeal procedure, conforming to the specifications of section 412 of the Health Care Quality Improvement Act (42 U.S.C. § 11112), for all determinations of the HII that are adverse to a health professional or provider, including but not limited to adverse reimbursement and network participation determinations. PARCA § 2777(a)(12).

95. Prior to taking any review action against a health professional or provider, make an official "reasonable belief" determination that the action is in furtherance of the quality of health care. PARCA § 2777(a)(12), incorporating 42 U.S.C. § 11112(a)(1).

96. Prior to taking any review action against a health professional or provider, make a "reasonable effort to obtain the facts of the matter." PARCA § 2777(a)(12), incorporating 42 U.S.C. § 11112(a)(2).

97. Prior to taking any review action against a health professional or provider, provide "adequate notice and hearing procedures" or "such other procedures as are fair to the [professional or provider] under the circumstances." PARCA § 2777(a)(12), incorporating 42 U.S.C. § 11112(a)(3).

98. Prior to taking any review action against a health professional or provider, make an official "reasonable belief" determination that the action is "warranted by the facts known after such reasonable effort to obtain facts" and after the hearing or other procedure. PARCA § 2777(a)(12), incorporating 42 U.S.C. § 11112(a)(4).

99. Prepare a "Notice of Proposed Review Action" containing the following elements: (i) statement that a professional review action has been proposed to be taken against the health professional or provider; (ii) statement of the reasons for the proposed action; (iii) statement that the professional or provider has the right to request a hearing on the proposed review action; (iv) statement of any time limit within which the professional or provider must request a
hearing; and (v) a summary of the professional's or provider's hearing rights. PARCA § 2777(a)(12), incorporating 42 U.S.C. § 11112(b)(1).

100. Prepare a "Notice of Hearing" containing the following elements: (i) the place, time and date of the hearing; and (ii) a list of witnesses expected to testify at the hearing on behalf of the review body. PARCA § 2777(a)(12), incorporating 42 U.S.C. § 11112(b)(2).

101. Identify: (i) an arbitrator for the hearing who is mutually acceptable to both the health professional/provider and the HII; (ii) a hearing officer who is not in direct economic competition with the health professional/provider under review; or (iii) a panel of individuals not in direct economic competition with the professional/provider involved. PARCA § 2777(a)(12), incorporating 42 U.S.C. § 11112(b)(3)(A).

102. Make arrangements for, and conduct, the hearing. PARCA § 2777(a)(12), incorporating 42 U.S.C. § 11112(b)(3)(C).

103. Make a transcript or other record of the hearing, and make copies of the transcript available to the health professional or provider. PARCA § 2777(a)(12), incorporating 42 U.S.C. § 11112(b)(3)(C)(ii).

104. Prepare, and provide to the health professional or provider, a written decision of the HII, including a statement of the basis for the decision. PARCA § 2777(a)(12), incorporating 42 U.S.C. § 11112(b)(3)(D)(ii).

105. Establish procedures for immediately and temporarily suspending a health professional or provider, subject to subsequent notice and hearing or other adequate procedures, where the failure to take such action could result in an imminent danger to the health of any individual. PARCA § 2777(a)(12), incorporating 42 U.S.C. § 11112(b)(3)(C)(ii).

106. Provide health professionals and providers with reasonable notice and explanation of decision to termination network participation. PARCA § 2777(a)(13)(A).

107. Provide health professionals and providers with an opportunity to review and discuss all of the information on which the termination decision was based. PARCA § 2777(a)(13)(B).

108. Prior to terminating a health professional or provider, provide him or her with an opportunity to enter into a corrective action plan. PARCA § 2777(a)(13)(C).
109. Promulgate a new regulatory definition of the term "enrollee," reflecting the fact that the PARCA definition differs from that used in the Medicare statute. The regulation would have to address conflicts or inconsistencies stemming from the two varying statutory definitions. PARCA § 2770(b)(1).

110. Promulgate a new regulatory definition of the term "health professional," reflecting the fact that the PARCA definition differs from that used in the Medicare statute. The regulation would have to address conflicts or inconsistencies stemming from the two varying statutory definitions. PARCA § 2770(b)(2).

111. Promulgate a new regulatory definition of the term "network," reflecting the fact that the PARCA definition differs from that used in HIPAA. The regulation would have to address conflicts or inconsistencies stemming from the two varying statutory definitions. PARCA § 2770(b)(3).

112. Promulgate a new regulatory definition of the term "network coverage," reflecting the fact that the PARCA definition differs from that used in HIPAA. The regulation would have to address conflicts or inconsistencies stemming from the two varying statutory definitions. PARCA § 2770(b)(4).

113. Promulgate a new regulatory definition of the term "participating." PARCA § 2770(b)(5).

114. Promulgate a new regulatory definition of the term "prior authorization," taking into account varying definitions under State laws. PARCA § 2770(b)(6).

115. Promulgate a new regulatory definition of the term "provider," taking into account varying definitions under State laws. PARCA § 2770(b)(7).

116. Promulgate a new regulatory definition of the term "service area," reflecting the fact that the PARCA definition differs from that used in the Medicare statute. The regulation would have to address conflicts or inconsistencies stemming from the two varying statutory definitions. PARCA § 2770(b)(8).

117. Promulgate a new regulatory definition of the term "utilization review." PARCA § 2770(b)(9).

118. Promulgate a new regulatory definition of the term "notice," taking into
account PARCA’s new enrollee notification requirements. PARCA § 2770(a).

119. Define "adequate arrangements" to ensure access, for use by self-insured plans. PARCA § 2771(a)(1).

120. Investigate reported violations of, and monitor compliance with, PARCA’s access provisions. PARCA § 2771(a).

121. Undertake administrative enforcement proceedings of violations of PARCA’s access provisions. PARCA § 2771(a).

122. Promulgate standards for determining what constitutes a "sufficient number, mix and distribution" of health professionals and providers. PARCA § 2771(a)(1).

123. Promulgate standards to enable HIIs to determine when the site adequacy and geographic site distribution requirements have been met. PARCA § 2771(a)(1)(B).

124. Promulgate standards to enable HIIs to determine whether the "reasonable promptness" of access requirement has been met in multiple health care contexts. PARCA § 2771(a)(1)(C).

125. Promulgate a regulation setting forth how an HII can achieve compliance with the residential proximity requirement, in light of constantly changing enrollee populations and unique geographical characteristics of each service area. PARCA § 2771(a)(1)(D).

126. Promulgate a regulation setting forth how an HII can achieve compliance with the obligation to take into account diverse enrollee needs in achieving access. PARCA § 2771(a)(1)(E)(i).

127. Promulgate standards for use in determining when an HII has provided adequate continuity of care. PARCA § 2771(a)(1)(E)(ii).

128. Promulgate a regulation governing the access obligations of HIIs with respect to underserved and rural populations. PARCA § 2771(a)(1).

129. Investigate reported violations of, and monitor compliance with, PARCA’s emergency and urgent care provisions. PARCA § 2771(b).

130. Undertake administrative enforcement proceedings of violations of PARCA’s emergency and urgent care provisions. PARCA § 2771(b).
131. Promulgate regulatory guidelines for use in determining whether the "prudent layperson" standard has been met with respect to emergency care services provided without prior authorization. The guidelines would have to enable utilization reviewers, providers and other decisionmakers to distinguish: (i) genuine emergency situations and nonemergency situations which nevertheless would appear to be emergencies to a "prudent layperson." PARCA § 2771(b)(2)(A).


133. Promulgate a regulation setting forth multiple situations in which specified kinds of specialized treatment expertise are called for. PARCA § 2771(c)(1) and (2).

134. Investigate reported violations of, and monitor compliance with, PARCA's specialized treatment provisions. PARCA § 2771(c).

135. Undertake administrative enforcement proceedings of violations of PARCA's specialized treatment provisions. PARCA § 2771(c).

136. Promulgate guidelines setting forth situations, including provider reimbursement scenarios, in which an HII will be deemed to have violated the prohibition against directly or indirectly inducing reductions or limits of medically necessary services. PARCA § 2771(d)(1).

137. Investigate reported violations of, and monitor compliance with, PARCA's health professional/provider incentive provisions. PARCA § 2771(d).

138. Undertake administrative enforcement proceedings of violations of PARCA's health professional/provider incentive provisions. PARCA § 2771(d).

139. Promulgate a regulation defining the term "substantial financial risk" for purposes of the prohibition against provider incentive plans. PARCA § 2771(d)(1)(B).

140. Promulgate standards for stop-loss protection to be provided by an HII to health professionals or providers to compensate for the financial risk associated with non-provided services. PARCA § 2771(d)(1)(B).

141. Promulgate standards setting forth what an HII must do to comply with the enrollee selection-of-provider and change-of-provider requirements. PARCA § 2772(a)(1).
142. Investigate reported violations of, and monitor compliance with, PARCA’s enrollee selection-of-provider and change-of-provider provisions. PARCA § 2772(a).


144. Promulgate standards for determining when a point-of-service option premium is "fair and reasonable." PARCA § 2772(b)(2).

145. Investigate reported violations of, and monitor compliance with, PARCA’s point-of-service option provisions. PARCA § 2772(b).

146. Undertake administrative enforcement proceedings of violations of PARCA’s point-of-service option provisions. PARCA § 2772(b).

147. Investigate reported violations of, and monitor compliance with, the requirements that: (i) non-network professionals and providers receive reimbursement not less than that of network participants; and (ii) non-network professionals and providers be permitted to engage in balance billing. PARCA § 2772(b)(3).

148. Undertake administrative enforcement proceedings of violations of the requirements that: (i) non-network professionals and providers receive reimbursement not less than that of network participants; and (ii) non-network professionals and providers be permitted to engage in balance billing. PARCA § 2772(b)(3).

149. Investigate reported violations of, and monitor compliance with, PARCA’s coordination-of-care provisions. PARCA § 2772(c).

150. Undertake administrative enforcement proceedings of violations of PARCA’s coordination-of-care provisions. PARCA § 2772(c).

151. Promulgate guidelines or standards to enable an HII to determine the range of circumstances under which a change of health professional or provider might disrupt the continuity of care for an enrollee. PARCA § 2772(c)(4).

152. Promulgate guidelines and standards for adoption by an HII to avoid enrollee discrimination. PARCA § 2773(a).

153. Investigate reported violations of, and monitor compliance with, PARCA’s enrollee discrimination provisions. PARCA § 2773(a).
154. Undertake administrative enforcement proceedings of violations of PARCA's enrollee discrimination provisions. PARCA § 2773(a).

155. Promulgate guidelines and standards for adoption by an HII to avoid health professional/provider discrimination. PARCA § 2773(b).

156. Investigate reported violations of, and monitor compliance with, PARCA's health professional/provider discrimination provisions. PARCA § 2773(b).

157. Undertake administrative enforcement proceedings of violations of PARCA's health professional/provider discrimination provisions. PARCA § 2773(b).

158. Promulgate guidelines setting forth multiple situations in which the provider-patient communications provisions will be deemed to have been violated, including through the issuance of 'no-action' letters in response to specific inquiries. PARCA § 2774(a) and (c)(1).

159. Investigate reported violations of, and monitor compliance with, PARCA's provider-patient communications provisions. PARCA § 2774(a).

160. Undertake administrative enforcement proceedings of violations of PARCA's provider-patient communications provisions. PARCA § 2774(a).

161. Investigate reported violations of, and monitor compliance with, PARCA's plan policy development provisions. PARCA § 2775.

162. Undertake administrative enforcement proceedings of violations of PARCA's plan policy development provisions. PARCA § 2775.

163. Promulgate standards setting forth what an HII must do to be in compliance with the requirement that health professionals and providers be integrated into the HII's utilization review process. PARCA § 2776(a)(1).

164. Investigate reported violations of, and monitor compliance with, PARCA's utilization review provisions. PARCA § 2776(a).

165. Undertake administrative enforcement proceedings of violations of PARCA's utilization review provisions. PARCA § 2776(a).

166. Promulgate guidelines on what kinds of utilization review criteria disclosures will be deemed to be consistent with protection of the HII's proprietary information. PARCA § 2776(a)(2).

167. Promulgate standards setting forth specific new medical developments that
must be taken into account in special utilization review contexts. PARCA § 2776(a)(3).

168. Promulgate guidelines for use by an HII in determining what information about individuals conducting utilization review can be released, and under what circumstances, as well as what "reasonable safeguards" can be implemented by the HII. PARCA § 2776(a)(5).

169. Promulgate guidelines setting forth specific situations in which an HII will be deemed to have compensated individuals conducting utilization review for denials of payment or coverage. PARCA § 2776(a)(6).

170. Promulgate standards setting forth language to be included in utilization determination notices concerning the right to appeal. PARCA § 2776(a)(9).

171. Promulgate a standard for determining when information provided to an HII for utilization review will be deemed sufficiently false so as to enable the HII to reverse its determination. PARCA § 2776(a)(10).

172. Promulgate a regulation setting forth the minimal requirements of the procedure for review of adverse utilization review and adverse care determinations. PARCA § 2776(b)(1) and (2).

173. Promulgate a regulation setting forth the minimum requirements of the network participation application process for health professionals and providers, including credentialing committee requirements and health professional/provider notice requirements. PARCA § 2777(a)(1).


175. Promulgate a standard setting forth legitimate economic considerations for use in selecting providers. PARCA § 2777(a)(6).

176. Promulgate standards for the uniform and objective adjustment of health professional and provider economic profiles. PARCA § 2777(a)(7).

177. Investigate reported violations of, and monitor compliance with, PARCA's plan-level provider due-process appeals provisions. PARCA § 2777(a)(12).


179. Promulgate a regulation setting forth the specific categories of services into
which information must be organized in HII informational and marketing materials. PARCA § 2778(a)(1)(A).

180. Investigate reported violations of, and monitor compliance with, PARCA’s information, reporting and disclosure provisions. PARCA § 2778(a).

181. Undertake administrative enforcement proceedings of violations of PARCA’s information, reporting and disclosure provisions. PARCA § 2778(a).

182. Promulgate a regulation setting forth the specific categories of health professionals and providers into which information must be organized in HII informational and marketing materials. PARCA § 2778(a)(1)(B).

183. Promulgate a uniform methodology for calculating the percentage of the premium charged by the plan that is set aside for administration and marketing. PARCA § 2778(a)(2).1

184. Promulgate a uniform methodology for calculating the percentage of the premium charged by the plan that is expended directly on patient care. PARCA § 2778(a)(3).

185. Promulgate a regulation setting forth a uniform format for the disclosure to enrollees and prospective enrollees of information about the ratio of enrollees to participating health professionals and providers by type of professional and provider. PARCA § 2778(a)(5).

186. Promulgate a regulation setting forth a uniform format for the disclosure to enrollees and prospective enrollees of information about the plan’s expenditures and utilization per enrollee by type of health professional and provider. PARCA § 2778(a)(6).

187. Promulgate a regulation setting forth a uniform format for the disclosure to enrollees and prospective enrollees of information about enrollee financial obligations for premiums, copayments and deductibles, including obligations for services provided by non-participating health professionals and providers and services provided to enrollees outside the service area. PARCA § 2778(a)(7).

188. Promulgate a regulation setting forth a uniform format for the disclosure to enrollees and prospective enrollees of information about financial/non-financial arrangements/incentives that could limit the items and services furnished to an enrollee, restrict referral or treatment options, or negatively affect the fiduciary responsibility of a health professional or provider to an enrollee. PARCA § 2778(a)(9) and (10).
189. Promulgate a regulation setting forth a uniform format for the disclosure to enrollees and prospective enrollees of information about quality indicators for the HII and participating health professionals and providers, including performance measures such as appropriate referrals and prevention of secondary complications following treatment. PARCA § 2778(a)(11).

190. Promulgate a regulation setting forth how an HII will be required to gather and report information about the percentage of utilization review determinations made by the HII that disagree with the judgment of the treating health professional or provider and the percentage of such determinations that are reversed on appeal. PARCA § 2778(a)(13).

191. Promulgate a regulation setting forth standards pertaining to the styles and sizes of type to be used in informational and marketing materials. PARCA § 2778(b)(1).

192. Promulgate a regulation setting forth standards for informational and marketing materials aimed at ensuring accessibility and comprehensibility. PARCA § 2778(b)(2).

193. Promulgate a regulation setting forth standards regarding the placement and positioning of information in health plan informational and marketing materials. PARCA § 2778(b)(2).

194. Investigate reported violations of, and monitor compliance with, PARCA's enrollee/provider confidentiality provisions. PARCA § 2779(a).

195. Undertake administrative enforcement proceedings of violations of PARCA's enrollee/provider confidentiality provisions. PARCA § 2779(a).

196. Promulgate a regulation identifying "individually identifiable information" subject PARCA's confidentiality requirements. PARCA § 2779(a)(2).

197. Promulgate a regulation identifying accreditation body standards compliance with which will constitute compliance with PARCA's quality improvement program requirements. PARCA § 2780(a)(1).

198. Investigate reported violations of, and monitor compliance with, PARCA's quality improvement provisions. PARCA § 2780(a).

199. Undertake administrative enforcement proceedings of violations of PARCA's quality improvement provisions. PARCA § 2780(a).

200. Make determinations, pursuant to sections 2722 and 2761 of the Public Health
Service Act, whether each State has failed to substantially enforce the provisions of PARCA pertaining to the group or individual health markets. 42 U.S.C. §§ 300gg-21, 300gg-45.
Mandates on State Insurance Departments

201. Promulgate (or enact), and enforce through investigative and penalty proceedings, regulations (or statutes) corresponding to all of the regulations set forth in Chapter Three and all of the oversight and enforcement obligations set forth at pages 43-51 above; or, alternatively, default in the enforcement of PARCA and defer to Federal enforcement. See Public Health Service Act §§ 2722, 2761 (42 U.S.C. §§ 300gg-21, 300gg-45).

202. Define "adequate arrangements" to ensure access, for use by insured plans. PARCA § 2771(a)(1).

203. Promulgate regulatory standards setting forth which specific health care items and services constitute "urgent care services" due to the fact that they "pose a danger to the patient if not treated in a timely manner." In developing such regulatory standards, the State must engage in "consultation with relevant treating health professionals or providers," which virtually guarantees that each State will have different standards, creating problems for HIIs serving more than one State. PARCA § 2771(b)(2)(C).

204. Consult with NAIC in establishing a regulatory definition of "fair and reasonable" with respect to premiums for point-of-service options. PARCA § 2772(b)(2).

205. Establish standards governing what constitute reasonable/undue burdens on enrollees with special health care needs or chronic conditions in the coordination of care and cost control contexts. PARCA § 2772(c)(1).

206. Monitor HII compliance with standards governing what constitute reasonable/undue burdens on enrollees with special health care needs or chronic conditions in the coordination of care and cost control contexts. PARCA § 2772(c)(1).

207. Promulgate regulations defining what constitutes "timely access" in the context of providing access to utilization review personnel. PARCA § 2776(a)(11).