Regulatory Requirements of "The Patients' Bill of Rights Act"

H.R. 3605/S. 1890

The Democratic Leadership Health Care Reform Legislative Proposal

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Introduction

MBS was asked by the Health Benefits Coalition to review the "Patients' Bill of Rights Act of 1998" (H.R. 3605/S. 1890, the Democratic Leadership health care reform legislative proposal), and answer the following questions:

• How many regulatory mandates would be imposed by the Patients’ Bill of Rights Act?

• How many new Federal causes of action would be created by the bill?

• How many new Federal regulations would have to be promulgated in order for the Patients’ Bill of Rights Act to become operational?

• How many new Federal full-time employees ("FTEs") would have to be hired to implement the Patients’ Bill of Rights Act? What new appropriations would be necessitated by such new staffing requirements?

As is documented more fully in the chapters that follow, MBS has arrived at the following conclusions:

• 359 mandates are contained in the Patients’ Bill of Rights Act. (See pages 2-47.)

  -- 196 of these mandates would be borne by health plans and issuers. (See pages 2-26.)

  -- 119 of these mandates would be borne jointly by the Departments of HHS and Labor. (See pages 29-41.)

  -- Additional mandates would be imposed on other Federal agencies, as well as on State governments. (See pages 42-47.)

• 56 new Federal causes of action would be created, at a minimum. (See pages 48-53.)

• 59 new Federal regulations would have to be promulgated, at a minimum. (See pages 54-61.)

• 3,828 new FTEs would have to be hired by the Federal Government to implement the Patients’ Bill of Rights Act. (See pages 62-67.)

• $155,294,304.00 per year in Congressional appropriations would be required to maintain this new staffing level.
Chapter One
New Mandates Under the Patients’ Bill of Rights Act

A. Mandates on Health Plans and Issuers.

1. Mandates on Health Plans and Issuers.

(1) When emergency services are covered, ensure that such services are furnished without the need for prior authorization determinations. § 101(a)(1)(A).

(2) When emergency services are covered, ensure that such services are furnished whether or not the health care provider furnishing the services is a participating provider with respect to such services. § 101(a)(1)(B).

(3) When emergency services are furnished by a nonparticipating provider, ensure that the participant, beneficiary or enrollee is not liable for amounts of liability that exceed the amounts for which the participant, beneficiary or enrollee would have been liable had the services been furnished by a participating provider. § 101(a)(1)(C)(i).

(4) When emergency services are furnished by a nonparticipating provider, ensure that the plan or issuer pays an amount that is equal to or greater than the amount that would have been paid to a participating provider (even if the nonparticipating provider charges less). § 101(a)(1)(C)(ii).

(5) Ensure that emergency services are provided without regard to any other coverage term or condition (except for an exclusion, coordination of benefits or affiliation/waiting period permitted under section 2701 of the Public Health Service Act, section 701 of ERISA, or section 9801 of the Internal Revenue Code). § 101(a)(1)(D).

(6) When authorization or reimbursement for emergency services are sought, determine whether such services are covered based on the "prudent layperson" standard. § 101(a)(2)(A).

(7) When authorization or reimbursement for emergency services are sought, determine whether such services come within the definition of "emergency services" in the Patients’ Bill of Rights Act. § 101(a)(2)(B).
When maintenance or post-stabilization care (covered under the guidelines established under section 1852(d)(2) of the Social Security Act) is provided by a nonparticipating provider, ensure that the participant, beneficiary or enrollee is not liable for amounts of liability that exceed the amounts for which the participant, beneficiary or enrollee would have been liable had the services been furnished by a participating provider. §§ 101(a)(1)(C)(i) and 101(b).

When maintenance care or post-stabilization care (covered under the guidelines established under section 1852(d)(2) of the Social Security Act) is provided by a nonparticipating provider, ensure that the plan or issuer pays an amount that is equal to or greater than the amount that would have been paid to a participating provider (even if the nonparticipating provider charges less). §§ 101(a)(1)(C)(ii) and 101(b).

Defend against administrative and judicial complaints alleging that the plan or issuer has violated the emergency care provisions of section 101 of the Act. § 101.

Offer group network plan participants the option to purchase point-of-service coverage for all benefits otherwise limited to coverage through the network. Ensure that such point-of-service options are offered at the time of enrollment and whenever the plan or issuer offers the participant a choice of coverage options. § 102(a)(1).

Defend against administrative and judicial complaints alleging that the plan or issuer has violated the point-of-service provisions of section 102 of the Act. § 102.

Ensure that each participant, beneficiary or enrollee is permitted to receive primary care from the participating primary care provider of his or her choice, so long as that provider is available to accept the participant, beneficiary or enrollee. § 103(a).

Permit each participant, beneficiary or enrollee to receive medically necessary or appropriate specialty care, pursuant to appropriate referral procedures, from any qualified participating health care provider who is available to accept such individual for such care. § 103(b)(1).

Defend against administrative and judicial complaints alleging that the plan or issuer has violated the choice-of-provider provisions of section 103 of the Act. § 103.

Permit a female participant, beneficiary or enrollee to designate a
participating physician who specializes in obstetrics and gynecology to be her primary care provider. § 104(a)(1)(A).

(17) To the extent that a female participant, beneficiary or enrollee has not designated an obstetrician or gynecologist as her primary care provider, ensure that the plan or issuer does not require authorization or referral by the individual's primary care provider or otherwise for coverage of routine gynecological care (such as preventive women's health examinations) and pregnancy-related services provided by a participating obstetrician or gynecologist. § 104(a)(1)(B)(i).

(18) Ensure that referral to an available and accessible specialist is provided whenever: (i) a participant, beneficiary or enrollee has a condition or disease of sufficient seriousness and complexity to require treatment by a specialist; and (ii) benefits for such treatment are covered. § 104(b)(1)(A).

(19) Ensure that treatment plans for the provision of specialty care are developed by specialists in consultation with the both the patient and his or her designated primary care provider. § 104(b)(1)(C)(i).

(20) Ensure that treatment plans for the provision of specialty care are developed in accordance with applicable quality assurance and utilization review standards of the plan or issuer. § 104(b)(1)(C)(ii).

(21) When specialty care is required within the meaning of section 104(b)(1)(A), but an appropriate participating specialist is not available and accessible, provide for referral to a nonparticipating specialist. § 104(b)(1)(D).

(22) When specialty care is furnished by a nonparticipating provider, ensure that the patient is not charged more than what the patient would have been charged had the specialist been a participating provider. § 104(b)(1)(E).

(23) Ensure that a participant, beneficiary or enrollee with "ongoing special conditions" is permitted to receive referral to a specialist for his or her condition who shall be responsible for and capable of providing and coordinating his or her primary and specialty care. § 104(b)(2)(A).

(24) When a specialist is designated to serve as the primary physician for providing and coordinating primary and specialty care to an individual with an "ongoing special condition," permit such specialist: (i) to treat the individual without referral from the individual's original primary
care provider; and (ii) to authorize such referrals, procedures, tests and other medical services as the individual’s primary care provider would otherwise be permitted to provide or authorize (subject to the terms of the treatment plan). § 104(b)(2)(B).

(25) Establish a procedure by which a participant, beneficiary or enrollee with a condition requiring ongoing care from a specialist may receive a standing referral to such specialist for treatment of the ongoing condition. § 104(b)(3)(A).

(26) Ensure compliance with the standing referral procedure established pursuant to section 104(b)(3)(A) by making standing referrals as appropriate and in accordance with the procedure. § 104(b)(3)(B).

(27) Defend against administrative and judicial complaints alleging that the plan or issuer has violated the specialty care provisions of section 104 of the Act. § 104.

(28) If a contract with a provider is terminated, or benefits provided by a provider are terminated because of a change in provider participation in the plan, and a plan participant, beneficiary or enrollee is undergoing a course of treatment from the provider at the time of such termination: (i) notify the individual on a timely basis of such termination; and (ii) provide continuity of coverage for the treatment for the applicable transitional period (which is usually 90 days from the date of notice). § 105(a)(1).

(29) If a contract between a group plan and a health insurance issuer is terminated, and as a result of such termination, coverage of services of a provider is terminated with respect to an individual who is undergoing a course of treatment from the provider at the time of such termination: (i) notify the individual on a timely basis of such termination; and (ii) provide continuity of coverage for the treatment for the applicable transitional period (but only with respect to benefits that are covered by the plan after the contract termination). § 105(a)(2).

(30) Defend against administrative and judicial complaints alleging that the plan or issuer has violated the continuity of care provisions of section 105 of the Act. § 105.

(31) Determine which individuals constitute "qualified individuals" and which clinical research studies/investigations constitute "clinical trials" within for purposes of section 106, based on guidance to be promulgated by HHS. § 106.
Ensure that a "qualified individual" (within the meaning of section 106(b)) is not denied participation in a clinical trial (meeting the requirements of section 106). § 106(a)(1)(A).

Ensure that a "qualified individual" (within the meaning of section 106(b)) participating in a clinical trial (meeting the requirements of section 106) is not denied coverage of routine patient costs for items and services furnished in connection with participation in such clinical trial. § 106(a)(1)(B).

Ensure that the plan or issuer does not discriminate against an individual on the basis of his or her participation in a clinical trial. § 106(a)(1)(C).

Defend against administrative and judicial complaints alleging that the plan or issuer has violated the clinical trial provisions of section 106 of the Act. § 106.

To the extent that the plan or issuer provides prescription drug benefits, but limits such benefits to drugs included in a formulary, ensure the participation of participating physicians and pharmacists in the development of the formulary. § 107(a)(1).

To the extent that the plan or issuer provides prescription drug benefits, but limits such benefits to drugs included in a formulary, disclose to providers (and, upon request, to plan participants, beneficiaries and enrollees) the nature of the formulary restrictions. § 107(a)(2).

If the plan or issuer provides prescription drug benefits, but limits such benefits to drugs included in a formulary, provide for exceptions from the formulary limitation (consistent with the standards of the plan's utilization review program under section 115). § 107(a)(3).

If the plan provides coverage of prescription or medical devices, ensure that coverage is not denied in the case of a prescription drug included in the labeling authorized by an application in effect pursuant to section 505(b) or (j) of the Federal Food, Drug, and Cosmetic Act, without regard to any post-marketing requirements that may apply under the Act. § 107(b)(1)(A)(i).

If the plan provides coverage of prescription or medical devices, ensure that coverage is not denied in the case of a prescription drug included in the labeling authorized by an application in effect for the drug under section 351 of the Public Health Service Act (without regard to any post-
marketing requirements that may apply pursuant to such section). § 107(b)(1)(A)(i).

(41) If the plan provides coverage of prescription or medical devices, ensure that coverage is not denied in the case of a medical device included in the labeling authorized by a regulation under subsection (d) or (3) of section 513 of the Federal Food, Drug, and Cosmetic Act, an order under subsection (f) of such section, or an application approved under section 515 of such Act (without regard to any post-marketing requirements that may apply under such Act). § 107(b)(1)(B).

(42) Defend against administrative and judicial complaints alleging that the plan or issuer has violated the prescription drug coverage provisions of section 107 of the Act. § 107.

(43) Ensure that the plan’s or coverage’s network has (in relation to coverage) a sufficient number, distribution and variety of qualified participating health care providers to ensure that all covered health care services, including specialty services, will be available and accessible in a timely manner to all participants, beneficiaries and enrollees under the plan or coverage. § 108(a).

(44) To the extent necessary to ensure network adequacy, include in the plan’s or coverage’s network Federally qualified health centers, rural health clinics, migrant health centers, and other essential community providers located in the service area. § 108(b).

(45) Defend against administrative and judicial complaints alleging that the plan or issuer has violated the network adequacy provisions of section 108 of the Act. § 108.

(46) Ensure that the plan or issuer does not discriminate against a participant, beneficiary or enrollee in the delivery of health care services consistent with the covered benefits or as required by law based on race, color, ethnicity, national origin, religion, sex, age, mental or physical disability, sexual orientation, genetic information or source of payment. § 109(a).

(47) Defend against administrative and judicial complaints alleging that the plan or issuer has violated the patient nondiscrimination provisions of section 109 of the Act. § 109.

(48) Establish and maintain an ongoing, internal quality assurance and continuous quality improvement program. § 111(a).
Ensure that, as part of the internal quality assurance program, the plan or issuer maintains a separate, identifiable unit responsible for administration of the program. § 111(b)(1).

Ensure that, as part of the internal quality assurance program, the plan or issuer has a written plan for the program that is updated annually and that specifies: (i) activities to be conducted; (ii) organizational structure; (iii) duties of the medical director; and (iv) criteria and procedures for assessment of quality. § 111(b)(2).

Ensure that the plan's or issuer's quality assurance program provides for the systematic review of: (i) the type of health services provided; (ii) consistency of services provided with good medical practice; and (iii) patient outcomes. § 111(b)(3).

Ensure that the plan's or issuer's quality assurance program: (i) uses quality criteria based on performance and patient outcomes where feasible and appropriate; (ii) includes quality criteria that are directed specifically at meeting the needs of at-risk populations and covered individuals with chronic conditions or severe illnesses, including gender-specific criteria and pediatric-specific criteria where available and appropriate; (iii) includes methods for informing covered individuals of the benefit of preventive care and what specific benefits with respect to preventive care are covered under the plan or coverage; and (iv) makes available to the public a description of the quality criteria. § 111(b)(4).

Ensure that the plan's or issuer's quality assurance program has procedures for the reporting of possible quality concerns by providers and enrollees and for remedial actions to correct quality problems, including written procedures for responding to concerns and taking appropriate corrective action. § 111(b)(5).

Ensure that the plan's or issuer's quality assurance program provides for an analysis of the plan's or issuer's performance on quality measures (based on data collected under section 112). § 111(b)(6).

Ensure that the plan's or issuer's quality assurance program provides for a drug utilization review program (in accordance with section 114). § 111(b)(7).

Defend against administrative and judicial complaints alleging that the plan or issuer has violated the internal quality assurance program provisions of section 111 of the Act. § 111.
Collect aggregate utilization data, as part of the uniform data set. § 112(b)(1).

Collect data on the demographic characteristics of participants, beneficiaries and enrollees, as part of the uniform data set. § 112(b)(2).

Collect data on disease-specific and age-specific mortality rates and (to the extent feasible) morbidity rates of participants, beneficiaries and enrollees, as part of the uniform data set. § 112(b)(3).

Collect data on the satisfaction of participants, beneficiaries and enrollees, as part of the uniform data set. § 112(b)(4).

Collect data on quality indicators and health outcomes, including, to the extent feasible and appropriate, data on pediatric cases and on a gender-specific basis, as part of the uniform data set. § 112(b)(5).

Disclose all uniform data set data available to participants, beneficiaries and enrollees pursuant to the "patient information" provisions of section 121. § 112(c).

Provide all uniform data set data to HHS. § 112(c).

Defend against administrative and judicial complaints alleging that the plan or issuer has violated the standardized data collection provisions of section 112 of the Act. § 112.

Establish and maintain a written process for the selection of participating providers, including minimum professional requirements. § 113(a).

Include in the provider selection process verification of a provider's license and a history of suspension or revocation of the license. § 113(b).

Ensure that the provider selection process does not use a high-risk patient base or location of a provider in an area with residents with poorer health status as a basis for excluding providers from participation. § 113(c).

Ensure that the plan's or issuer's provider selection process does not discriminate with respect to participation or indemnification against any provider 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. § 113(d)(1).
(69) Ensure that the plan's or issuer's provider selection process does not discriminate with respect to the selection of participating providers, or with respect to the terms and conditions of such participation, based on a provider's race, color, religion, sex, national origin, age, sexual orientation, or disability (consistent with the Americans with Disabilities Act). § 113(e)(1).

(70) Defend against administrative and judicial complaints alleging that the plan or issuer has violated the provider selection provisions of section 113 of the Act. § 113.

(71) To the extent that the plan or issuer provides coverage for prescription drugs, establish and maintain, as part of the internal quality assurance and continuous quality improvement program under section 111, a drug utilization program which: (i) encourages appropriate use of prescription drugs by participants, beneficiaries and enrollees and providers; and (ii) takes appropriate action to reduce the incidence of improper drug use and adverse drug reactions and interactions. § 114.

(72) Defend against administrative and judicial complaints alleging that the plan or issuer has violated the drug utilization review provisions of section 114 of the Act. § 114.

(73) Ensure that all utilization review activities are carried out in full compliance with a written utilization review program under section 115. § 115(a)(1) and (b)(1).

(74) Ensure that utilization review activities conducted on behalf of the plan or issuer by outside agents are carried out in full compliance with the plan's or issuer's utilization review program under section 115. § 115(a)(2).

(75) Develop and utilize written criteria as part of the utilization review program. § 115(b)(2)(A).

(76) Obtain input from "appropriate physicians" in developing the written criteria for the utilization review program. § 115(b)(2)(A).

(77) Include in the written criteria clinical review criteria directed specifically at meeting the needs of at-risk populations and covered individuals with chronic conditions or severe illnesses, including gender-specific criteria and pediatric-specific criteria where available and appropriate. §§ 115(b)(2) and 111(b)(4)(B).
If a health care service has been specifically pre-authorized or approved for an enrollee pursuant to a utilization review program, ensure that the program does not, pursuant to retrospective review, revise or modify the specific standards, criteria or procedures used for the utilization review for procedures, treatment or services delivered to the enrollee during the same course of treatment. § 115(b)(2)(B).

Ensure that the utilization review program is administered by qualified health care professionals who shall oversee review decisions. Ensure that such health care professionals are physicians or other health care practitioners licensed, accredited or certified to perform specified health services consistent with State law. § 115(c)(1).

Ensure that all personnel involved in utilization review activities are qualified, and, to the extent required, have received appropriate training in the conduct of such activities under the program. § 115(c)(2).

Ensure that "clinical peers" evaluate the clinical appropriateness of at least a sample of adverse clinical determinations made by the plan's or issuer's utilization review program. § 115(c)(2)(B).

Ensure that the utilization review program does not, with respect to utilization review activities, permit or provide compensation or anything of value to its employees, agents or contractors in a manner that: (i) provides incentives, direct or indirect, for such persons to make inappropriate review decisions; or (ii) is based, directly or indirectly, on the quantity or type of adverse determinations rendered. § 115(c)(2)(C).

Ensure that the utilization review program does not permit a health care professional who provides health care services to an individual to perform utilization review activities in connection with the health care services being provided to the individual. § 115(c)(2)(D).

Ensure that the utilization review program provides that appropriate personnel performing utilization review activities under the program are reasonably accessible by toll-free telephone during normal business hours to discuss patient care and allow response to telephone requests, and that appropriate provision is made to receive and respond promptly to calls received during other hours. § 115(c)(3).

Ensure that the utilization review program does not provide for the performance of utilization review activities with respect to a class of services furnished to an individual more frequently than is reasonably required to assess whether the services under review are medically
necessary or appropriate. § 115(c)(4).

(86) Ensure that, under the plan's or issuer's utilization review program, information shall be provided by a health care provider only to the extent necessary to perform the specific utilization review activity at hand. § 115(c)(5).

(87) Ensure that, under the plan's or issuer's utilization review program, a participant, beneficiary or enrollee who is dissatisfied with a preliminary utilization review decision has the opportunity to discuss the decision with, and have such decision reviewed by, the medical director of the plan or issuer involved (or the director's designee) who shall have the authority to reverse the decision. § 115(c)(6).

(88) Ensure, in the case of a utilization review activity involving the prior authorization of health care items and services for an individual, that the utilization review program makes its determination, and provides notice of the determination to the concerned individual (or his or her designee) and his or her health care provider by telephone and in printed form, as soon as possible in accordance with the medical exigencies of the cases, and in no event later than three business days after the date of receipt of information that is reasonably necessary to make such determination. § 115(d)(1).

(89) Ensure, in the case of a utilization review activity involving authorization for continued or extended health care services for an individual, or additional services for an individual undergoing a course of continued treatment prescribed by a health care provider, that the utilization review program shall make its determination concerning such authorization, and provide notice of the determination to the individual (or his or her designee) and his or her health care provider by telephone and in printed form, as soon as possible in accordance with the medical exigencies of the cases, and in no event later than one business day after the date of receipt of information that is reasonably necessary to make such determination. The notice must include, with respect to continued or extended health care services, the number of extended services approved, the new total of approved services, the date of onset of services, and the next review date, if any. § 115(d)(2).

(90) Ensure, in the case of a utilization review activity involving retrospective review of health care services previously provided for an individual, that the utilization review program shall make its determination, and provide notice of the determination to the individual (or his or her designee) and his or her health care provider by telephone
and in printed form, within 30 days of the date of receipt of information that is reasonably necessary to make such determination. § 115(d)(3).

Ensure that an adverse determination under a utilization review program shall be provided in printed form and shall include: (i) the reasons for the determination (including the clinical rationale); (ii) instructions on how to initiate an appeal; (iii) notice of the availability, upon request of the individual (or his or her designee) of the clinical review criteria relied upon to make such determination; and (iv) any additional information that must be provided to, or obtained by, the person making the determination in order to make a decision on appeal. § 115(e)(1) and (e)(2).

Defend against administrative and judicial complaints alleging that the plan or issuer has violated the utilization review provisions of section 115 of the Act. § 115.

Provide to participants, beneficiaries and enrollees at the time of initial coverage or enrollment (or the effective date of the Patients’ Bill of Rights Act for existing group plan participants and beneficiaries as of that date), and at least annually thereafter, the information set forth in section 121(b) pertaining to service area, benefits, access, out-of-area coverage, emergency coverage, loss ratios, prior authorization rules, grievance and appeals procedures, quality assurance, provider financial incentives, issuer information, and availability of additional information upon request. § 121(a)(1)(A) and (a)(2)(A).

Provide to participants, beneficiaries and enrollees information about significant changes in the information set forth in section 121(b) within a reasonable period of time before or after the date of such changes. § 121(a)(1)(B) and (a)(2)(B).

Upon request, make available to participants, prospective participants, beneficiaries, prospective beneficiaries, prospective enrollees and applicable regulatory authorities the information set forth in section 121(b) and (c) in printed form. § 121(a)(1)(C) and (a)(2)(C).

Include in the information package provided to participants, prospective participants, beneficiaries, prospective beneficiaries, enrollees, prospective enrollees and regulatory authorities information on the service area of the plan or issuer. § 121(b)(1).

Include in the information package provided to participants, prospective participants, beneficiaries, prospective beneficiaries, enrollees,
prospective enrollees and regulatory authorities information on covered benefits, including benefit limits and coverage exclusions. § 121(b)(2)(A).

(98) Include in the information package provided to participants, prospective participants, beneficiaries, prospective beneficiaries, enrollees, prospective enrollees and regulatory authorities information on cost sharing, such as deductibles, coinsurance, and copayment amounts, including any liability for balance billing, any maximum limitations on out-of-pocket expenses, and the maximum out-of-pocket costs for services that are provided by nonparticipating providers or that are furnished without meeting the applicable utilization review requirements. § 121(b)(2)(B).

(99) Include in the information package provided to participants, prospective participants, beneficiaries, prospective beneficiaries, enrollees, prospective enrollees and regulatory authorities information on the extent to which benefits may be obtained from nonparticipating providers. § 121(b)(2)(C).

(100) Include in the information package provided to participants, prospective participants, beneficiaries, prospective beneficiaries, enrollees, prospective enrollees and regulatory authorities information on the extent to which a participant, beneficiary, or enrollee may select from among participating providers and the types of providers participating in the plan or issuer network. § 121(b)(2)(D).

(101) Include in the information package provided to participants, prospective participants, beneficiaries, prospective beneficiaries, enrollees, prospective enrollees and regulatory authorities information on the process for determining experimental coverage. § 121(b)(2)(E).

(102) Include in the information package provided to participants, prospective participants, beneficiaries, prospective beneficiaries, enrollees, prospective enrollees and regulatory authorities information on the use of a prescription drug formulary. § 121(b)(2)(F).

(103) Include in the information package provided to participants, prospective participants, beneficiaries, prospective beneficiaries, enrollees, prospective enrollees and regulatory authorities a description of the number, mix and distribution of providers under the plan or coverage. § 121(b)(3)(A).

(104) Include in the information package provided to participants, prospective participants, beneficiaries, prospective beneficiaries, enrollees,
prospective enrollees and regulatory authorities a description of out-of-network coverage (if any) provided by the plan or coverage. § 121(b)(3)(B).

Include in the information package provided to participants, prospective participants, beneficiaries, prospective beneficiaries, enrollees, prospective enrollees and regulatory authorities a description of any point-of-service option (including any supplemental premium or cost-sharing for such option). § 121(b)(3)(C).

Include in the information package provided to participants, prospective participants, beneficiaries, prospective beneficiaries, enrollees, prospective enrollees and regulatory authorities a description of the procedures for participants, beneficiaries and enrollees to select, access and change participating primary and specialty providers. § 121(b)(3)(D).

Include in the information package provided to participants, prospective participants, beneficiaries, prospective beneficiaries, enrollees, prospective enrollees and regulatory authorities a description of the rights and procedures for obtaining referrals (including standing referrals) to participating and nonparticipating providers. § 121(b)(3)(E).

Include in the information package provided to participants, prospective participants, beneficiaries, prospective beneficiaries, enrollees, prospective enrollees and regulatory authorities a description of the name, address and telephone number of participating health care providers and an indication of whether each such provider is available to accept new patients. § 121(b)(3)(F).

Include in the information package provided to participants, prospective participants, beneficiaries, prospective beneficiaries, enrollees, prospective enrollees and regulatory authorities a description of any limitations imposed on the selection of qualifying participating health care providers, including any limitations imposed under section 103(b)(2). § 121(b)(3)(G).

Include in the information package provided to participants, prospective participants, beneficiaries, prospective beneficiaries, enrollees, prospective enrollees and regulatory authorities a description of how the plan or issuer addresses the needs of participants, beneficiaries and enrollees and others who do not speak English or who have other special communications needs in accessing providers under the plan or
coverage, including the provision of information described in section 121(b) and (c) to such individuals and including the provision of information in a language other than English if 5% of the number of participants, beneficiaries and enrollees communicate in that language instead of English. § 121(b)(3)(H).

(111) Include in the information package provided to participants, prospective participants, beneficiaries, prospective beneficiaries, enrollees, prospective enrollees and regulatory authorities information on out-of-area coverage provided by the plan or issuer. § 121(b)(4).

(112) Include in the information package provided to participants, prospective participants, beneficiaries, prospective beneficiaries, enrollees, prospective enrollees and regulatory authorities information on emergency services, including the appropriate use of emergency services (including use of the 911 telephone system or its local equivalent in emergency situations and an explanation of what constitutes an emergency situation). § 121(b)(5)(A).

(113) Include in the information package provided to participants, prospective participants, beneficiaries, prospective beneficiaries, enrollees, prospective enrollees and regulatory authorities information on the process and procedures of the plan or issuer for obtaining emergency services. § 121(b)(5)(B).

(114) Include in the information package provided to participants, prospective participants, beneficiaries, prospective beneficiaries, enrollees, prospective enrollees and regulatory authorities information on the locations of emergency departments and other settings in which plan physicians and hospitals provide emergency services and post-stabilization care. § 121(b)(5)(C).

(115) Include in the information package provided to participants, prospective participants, beneficiaries, prospective beneficiaries, enrollees, prospective enrollees and regulatory authorities a description of the overall loss ratio for the coverage (as defined by HHS). § 121(b)(6).

(116) Include in the information package provided to participants, prospective participants, beneficiaries, prospective beneficiaries, enrollees, prospective enrollees and regulatory authorities information on rules regarding prior authorization or other review requirements that could result in noncoverage or nonpayment. § 121(b)(7).

(117) Include in the information package provided to participants, prospective
participants, beneficiaries, prospective beneficiaries, enrollees, prospective enrollees and regulatory authorities information on all appeal and grievance rights and procedures under the plan or coverage, including: (i) the method for filing grievances; (ii) the time frames and circumstances for acting on grievances and appeals; (iii) applicable authority within the plan or issuer; and (iv) the availability of assistance through an ombudsman. § 121(b)(8).

(118) Include in the information package provided to participants, prospective participants, beneficiaries, prospective beneficiaries, enrollees, prospective enrollees and regulatory authorities a summary description of the data on quality collected under section 112(a), including a summary description of the satisfaction data (including data on voluntary disenrollment, grievances and appeals set forth in section 112(b)(4)). § 121(b)(9).

(119) Include in the information package provided to participants, prospective participants, beneficiaries, prospective beneficiaries, enrollees, prospective enrollees and regulatory authorities a summary description of the information on the types of financial payment incentives provided by the plan or issuer in connection with the coverage. § 121(b)(10).

(120) Include in the information package provided to participants, prospective participants, beneficiaries, prospective beneficiaries, enrollees, prospective enrollees and regulatory authorities appropriate mailing addresses and telephone numbers to be used by participants, beneficiaries and enrollees seeking information or authorization for treatment. § 121(b)(11).

(121) Include in the information package provided to participants, prospective participants, beneficiaries, prospective beneficiaries, enrollees, prospective enrollees and regulatory authorities notice that the information described in section 121(c) is available upon request. § 121(b)(12).

(122) Make available upon request a description of procedures used and requirements (including circumstances, time frames and appeal rights) under any applicable utilization review program (including drug formulary programs). § 121(c)(1).

(123) Make available upon request information on the number of grievances and appeals and on the aggregate disposition of such grievances and appeals. § 121(c)(2).
Make available upon request an overall summary description as to the method of compensation of participating physicians, including information on the types of financial payment incentives provided by the plan or issuer under the coverage. § 121(c)(3).

Make available upon request a description of the credentials of each participating provider. § 121(c)(4).

Make available upon request a description of the policies and procedures established to protect patient confidentiality. § 121(c)(5).

Make available upon request a description of the nature of any drug formula[ry] restrictions. § 121(c)(6).

Make available upon request a list of current participating health care providers. § 121(c)(7).

Ensure that information required to be disclosed to all participants, beneficiaries, enrollees and regulatory authorities under section 121 is disclosed in accordance with the uniform, national reporting standards established by the Secretary of HHS. § 121(d)(1).

Ensure that the information on participating health care providers required to be provided to participants, beneficiaries and enrollees is updated within such reasonable period as is determined appropriate by the Secretary of HHS. § 121(d)(3).

Defend against administrative and judicial complaints alleging that the plan or issuer has violated the patient information provisions of section 121 of the Act. § 121.

Establish procedures to safeguard the privacy of any individually identifiable enrollee information. § 122(1).

Establish procedures to maintain any individually identifiable enrollee information in a manner that is accurate and timely. § 122(2).

Establish procedures to assure timely access of enrollees to individually identifiable enrollee information. § 122(3).

Defend against administrative and judicial complaints alleging that the plan or issuer has violated the patient confidentiality protection provisions of section 122 of the Act. § 122.

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Establish and maintain a system to provide for the presentation and resolution of oral and written grievances brought by participants, beneficiaries and enrollees (or individuals acting on their behalf and with their consent) regarding any aspect of a plan's or issuer's services. § 131(a)(1).

Ensure that the grievance system includes grievances regarding access and availability of services, quality of care, choice and accessibility of providers, network adequacy, and compliance with all other requirements of the Patients' Bill of Right Act. § 131(a)(2).

As part of the grievance system, provide written notification to all participants, beneficiaries and enrollees of the telephone numbers and business addresses of the plan or issuer personnel responsible for resolution of grievances and appeals. § 131(b)(1).

As part of the grievance system, establish a system to record, document and maintain for three years all grievances and appeals (including their status). § 131(b)(2).

As part of the grievance system, process and resolve all grievances in a timely manner. § 131(b)(3).

As part of the grievance system, establish and carry out procedures for follow-up action, including procedures to inform aggrieved individuals as to how their grievances are resolved. § 131(b)(4).

As part of the grievance system, notify the plan's or issuer's continuous quality improvement program of all grievances and appeals pertaining to quality of care. § 131(b)(5).

Defend against administrative and judicial complaints alleging that the plan or issuer has violated the grievance procedures provisions of section 131 of the Act. § 131.

Establish an internal appeal procedure under which participants, beneficiaries and enrollees (or persons acting on their behalf and with their consent) can file written appeals of "appealable decisions," pertaining to payments, coverage, access, provider choice, quality of care, continuity of care, clinical trial costs, discrimination, utilization review and good medical practice. § 132(a) and (b)(1).

Upon receiving notice that a participant, beneficiary or enrollee is filing an internal appeal, provide the individual with a written explanation of
the appeal process. § 132(a)(1).

(146) Provide individuals filing internal appeals with written determinations at the conclusion of the appeal process. If the appeal is denied, the notice must be in printed form, set forth the reasons for the denial, and include a notice of any rights of further appeal. § 132(a)(1) and (b)(4).

(147) As part of the internal appeal process, ensure that the decision which is the subject of the appeal is reviewed by a physician or other health care professional who has been selected by the plan or issuer and who has not been involved in the decision which is the subject of the appeal. § 132(b)(2)(A).

(148) As part of the internal appeal process, ensure that the individuals conducting internal appeal reviews include one or more "clinical peers" (as defined pursuant to section 191(c)(2)) who have not been involved in the appealable decision at issue in the appeal. § 132(b)(2)(B).

(149) As part of the internal appeal process, ensure that each internal appeal is completed as soon as possible after the time of the receipt of the appeal in accordance with the medical exigencies of the case involved, but in no event later than: (i) 72 hours after the time of receipt of an expedited appeal; and (ii) 15 business days after the receipt of a non-expedited appeal. § 132(b)(3)(A).

(150) As part of the internal appeal process, obtain authorization from the applicable regulatory for an additional ten days to conduct a non-expedited internal appeal, based upon submission to both the regulatory authority and the aggrieved party of a written progress report and explanation for the delay demonstrating that the delay is beyond the control of the plan or issuer. § 132(b)(3)(B).

(151) Establish an expedited review process for internal appeals to apply whenever application of the normal timeframe for making an internal appeal determination could seriously jeopardize the life or health of the participant, beneficiary, or enrollee or such an individual's ability to regain maximum function. § 132(c)(1).

(152) As part of the expedited review process, ensure that expedited appeal requests are accepted in both oral and written form. § 132(c)(2)(A).

(153) As part of the expedited review process, ensure that all necessary information is transmitted between the plan/issuer and the requester by telephone, facsimile or other similarly expeditious available means. §
132(c)(2)(B).

As part of the expedited review process, ensure that the appeal is treated on an expedited basis whenever the request is made by a physician and the physician indicates in the request that application of the normal timeframe for making an internal appeal determination could seriously jeopardize the life or health of the participant, beneficiary, or enrollee or such an individual's ability to regain maximum function. § 132(c)(2)(C).

Defend against administrative and judicial complaints alleging that the plan or issuer has violated the internal appeals provisions of section 132 of the Act. § 132.

Establish and maintain an external appeals process under which participants, beneficiaries and enrollees can appeal to an outside entity internal appeals that: (i) exceed a threshold dollar amount; or (ii) involve jeopardy to the patient's life or health. § 133(a).

As part of the external appeals process, enter into a contract with one or more "qualified external appeal entities." § 133(b)(1)(A).

Ensure that contracts with "qualified external appeal entities" are consistent with the standards established by the appropriate regulatory body to assure that there is no real or apparent conflict of interest in the conduct of external appeal activities. § 133(b)(1)(C).

Ensure that contracts with "qualified external appeal entities" provide that the direct costs of the external appeal process (but not including the costs of representation of a participant, beneficiary or enrollee) shall be paid by the plan or issuer (and not by the participant, beneficiary or enrollee). § 133(b)(1)(C).

Provide timely access to all of the plan's or issuer's records relating to the subject matter of an externally appealable decision and to all provisions of the plan or issuer (including any coverage manual) relating to the matter. § 133(b)(2)(D).

Defend against administrative and judicial complaints alleging that the plan or issuer has violated the external appeals provisions of section 133 of the Act. § 133.

Ensure that the provisions of contracts or agreements between the plan or issuer (including any entity administering such contracts or
agreements) and a health care provider do not prohibit or restrict the provider from engaging in medical communications with the provider's patient. § 141(a)(1).

(163) Defend against administrative and judicial complaints alleging that the plan or issuer has violated the prohibition against restraints on medical communications of section 141 of the Act. § 141.

(164) Ensure that the provisions of contracts or agreements between the plan or issuer (including any entity administering such contracts or agreements) and a health care provider do not purport to transfer to the provider, by indemnification or otherwise, any liability relating to activities, actions or omissions of the plan, the issuer or an agent of the plan or issuer (as opposed to activities, actions or omissions of the provider). § 142(a)(1).

(165) Ensure that the plan or issuer does not operate any physician incentive plan (i.e., a plan or arrangement that would directly or indirectly have the effect of reducing or limiting services provided to patients), unless: (i) no specific payment is made directly or indirectly under the incentive plan/arrangement to a physician or physician group as an inducement to reduce or limit medically necessary services provided to the patient; (ii) if the incentive plan/arrangement places the physician at substantial financial risk for services not provided by the physician/physician group, then the health plan or issuer must (I) provide stop-loss protection for the physician/physician group, and (II) conduct periodic surveys of patient access and satisfaction; and (iii) the health plan/issuer provides the relevant regulatory authority with descriptive information regarding the incentive plan/arrangement sufficient to enable the authority to determine whether the incentive plan/arrangement is lawful. § 142(b)(1), incorporating by reference § 1876(i)(8) of the Social Security Act.

(166) Defend against administrative and judicial complaints alleging that the plan or issuer has violated the physician incentive limitations of section 142 of the Act. § 142.

(167) Establish reasonable procedures relating to the provision by the plan of notice to health care professionals of the plan's or issuer's rules regarding participation as a participating provider. § 143(a)(1).

(168) Establish reasonable procedures relating to the provision by the plan of written notice to health care professionals of participation decisions that are adverse to professionals. § 143(a)(2).
Establish reasonable procedures establishing a process within the plan or issuer for appealing such adverse decisions, including the presentation of information and views of the professional regarding such decision. § 143(a)(3).

Consult with participating physicians (if any) regarding the plan's or issuer's medical policy, quality and medical management procedures. § 143(b).

Defend against administrative and judicial complaints alleging that the plan or issuer has violated the provider credentialing provisions of section 143 of the Act. § 143.

Ensure that the plan or issuer does not retaliate against a participant, beneficiary, enrollee or provider based on the participant's, beneficiary's, enrollee's or provider's use of or participation in a utilization review process or grievance process of the plan or issuer (including an internal or external review or appeal process) under the Patients' Bill of Rights Act. § 144(a).

Establish and implement internal procedures to ensure that the plan or issuer does not retaliate against a "protected health care professional" or an "(protected) institutional provider" because the professional/provider, in good faith, discloses information relating to care, services or conditions affecting one or more patients to an appropriate regulatory agency, an appropriate accreditation body or appropriate management personnel of the plan or issuer. § 144(b)(1)(A).

Establish and carry out internal procedures to ensure that the plan or issuer does not retaliate against a "protected health care professional" or "(protected) institutional provider" because the professional/provider, in good faith, initiates, cooperates or otherwise participates in an investigation or proceeding by an appropriate regulatory agency regarding care, services or conditions affecting one or more patients. § 144(b)(1)(B).

Post a notice setting forth excerpts from or summaries of the pertinent "patient advocacy protection" provisions of the Patients' Bill of Rights. § 144(b)(5).

Defend against administrative and judicial complaints alleging that the plan or issuer has violated the patient advocacy protection provisions of section 144 of the Act. § 144.
(177) Establish and implement procedures to ensure that the plan or issuer does not arbitrarily interfere with or alter the decision of a treating physician regarding the manner or setting within which particular services are delivered if the services are medically necessary or appropriate for treatment or diagnosis, or to the extent that treatment is otherwise a covered benefit. § 151(a)(1).

(178) Defend against administrative and judicial complaints alleging that the plan or issuer has violated the good medical practice provisions of section 151 of the Act. § 151.

(179) Ensure that benefit packages providing coverage for hospital stays for mastectomies for the treatment of breast cancer include hospital stays in connection with such mastectomies of at least 48 hours. § 152(a)(1)(A)(i) and (c)(2).

(180) Ensure that benefit packages providing coverage for hospital stays for lymph node dissections for the treatment of breast cancer include hospital stays in connection with such lymph node dissections of at least 24 hours. § 152(a)(1)(A)(ii) and (c)(2).

(181) Establish and implement policies to ensure that providers are not required to obtain authorizations from plans or issuers for prescribing hospital stays in connection with mastectomies or lymph node dissections in connection with the treatment of breast cancer that do not exceed 48 hours and 24 hours respectively. § 152(a)(2).

(182) Establish and implement policies to ensure that women are not denied eligibility, or continued eligibility, to obtain or renew coverage solely for the purpose of complying with the breast cancer treatment provisions of the Patients' Bill of Rights Act. § 152(b)(1).

(183) Establish and implement policies to ensure that the plan or issuer does not provide monetary payments or rebates to women to encourage them to accept less than the minimum protections available under the breast cancer treatment provisions of the Patients' Bill of Rights Act. § 152(b)(2).

(184) Establish and implement policies to ensure that the plan or issuer does not penalize or otherwise reduce or limit the reimbursement of an attending provider because such provider provided care to an individual participant or beneficiary in accordance with the breast cancer treatment provisions of the Patients' Bill of Rights Act. § 152(b)(3).
Establish and implement policies to ensure that the plan or issuer does not provide incentives (monetary or otherwise) to an attending provider to induce such provider to provide care to an individual participant or beneficiary in a manner inconsistent with the breast cancer treatment provisions of the Patients' Bill of Rights Act. § 152(b)(4).

Establish and implement policies to ensure that a plan or issuer does not restrict benefits available for any portion of a period within a hospital length of stay required under section 152(a) (i.e., for mastectomies or lymph node dissections for the treatment of breast cancer) in a manner which is less favorable than the benefits provided for any preceding portion of such stay. § 152(b)(5).

Defend against administrative and judicial complaints alleging that the plan or issuer has violated the breast cancer treatment provisions of section 152 of the Act. § 152.

Ensure that benefit packages providing coverage for breast surgery in connection with a mastectomy provide coverage for reconstructive breast surgery resulting from the mastectomy, including coverage for all stages of reconstructive breast surgery performed on a nondiseased breast to establish symmetry with the diseased breast when reconstruction of the diseased breast is performed an coverage of prostheses and complications of mastectomy including lymphedema. § 153(a)(1) and (c)(2).

Establish and implement policies to ensure that the plan or issuer does not deny coverage for reconstructive breast surgery on the grounds that such surgery constitutes cosmetic surgery. § 153(b)(1).

Establish and implement policies to ensure that the plan or issuer does not provide monetary payments or rebates to women to encourage them to accept less than the minimum protections available under the reconstructive breast surgery provisions of the Patients' Bill of Rights Act. § 153(b)(2), incorporating § 152(b)(2).

Establish and implement policies to ensure that the plan or issuer does not penalize or otherwise reduce or limit the reimbursement of an attending provider because such provider provided care to an individual participant or beneficiary in accordance with the reconstructive breast surgery provisions of the Patients' Bill of Rights Act. § 153(b)(2), incorporating § 152(b)(3).

Establish and implement policies to ensure that the plan or issuer does
not provide incentives (monetary or otherwise) to an attending provider
to induce such provider to provide care to an individual participant or
beneficiary in a manner inconsistent with the reconstructive breast
surgery provisions of the Patients’ Bill of Rights Act. § 153(b)(2),
incorporating § 152(b)(4).

(193) Establish and implement policies to ensure that a plan or issuer does
not restrict benefits available for hospital stays in connection with
reconstructive breast surgery under section 153. § 153(b)(2),
incorporating § 152(b)(5).

(194) Establish and implement policies to ensure that a plan or issuer does
not impose deductibles, coinsurance or cost-sharing in connection with
benefits for reconstructive breast surgery that is greater than the
deductibles, coinsurance or cost-sharing in connection with
mastectomies. § 153(c)(3).

(195) Defend against administrative and judicial complaints alleging that the
plan or issuer has violated the reconstructive breast surgery provisions
of the Act. § 153.

(196) Defend against administrative and judicial complaints alleging that the
plan or issuer has violated provisions of Title I of the Patients’ Bill of
2. **Mandates on Qualified External Appeal Entities (to Be Paid for by Plans and Issuers).**

(197) Enter into contracts with plans and issuers to conduct external appeals. § 133(b)(1)(A).

(198) As part of the external appeal process, ensure that each external appeal is heard de novo and that the process for each external appeal is fair. § 133(b)(2)(A).

(199) As part of the external appeal process, determine: (i) whether the appeal is a valid, externally appealable decision; (ii) whether an expedited appeal is involved; (iii) the appropriate deadlines for internal review in light of any medical exigencies; and (iv) whether the internal review process has been completed. § 133(b)(2)(B).

(200) As part of the external appeal process, ensure that each party has an opportunity to: (i) submit and review evidence; (ii) use the assistance or representation of an attorney or other individual; and (iii) make an oral presentation. § 133(b)(2)(C).

(201) Provide written decisions resolving external appeals within 72 hours for expedited appeals and within 60 days for non-expedited appeals. § 133(b)(2)(E)(i) and (iii).

(202) Set forth in the written decision, in layperson's language, the basis for the determination, including, if relevant, any basis in the terms and conditions of the plan or coverage. § 133(b)(2)(E)(iv).

(203) Upon rendering a decision resolving an external appeal, inform the participant, beneficiary or enrollee of his or her rights to seek further review through the court system (or other process). § 133(b)(2)(E)(v).

(204) Ensure that there are no real or apparent conflicts of interest that would impede the entity in its conduct of external appeal activities independent of the plan or issuer. § 133(c)(1)(A).

(205) Ensure that the entity conducts all of its external appeal activities using "clinical peers." § 133(c)(1)(B).

(206) Ensure that the entity has sufficient medical, legal and other expertise and sufficient staffing to conduct external appeal activities for the plan or issuer on a timely basis. § 133(c)(1)(C).
Ensure that the entity meets any additional regulatory requirements established by the applicable regulatory authority. § 133(c)(1)(D).

Submit certification packages and periodic re-certification packages to the applicable regulatory authority. § 133(c)(2)(B).

As a prerequisite to re-certification, gather and maintain data on: (i) the number of cases reviewed; (ii) a summary of the disposition of those cases; (iii) the length of time in making determinations on those cases; (iv) information demonstrating the independence of the entity from plans or issuers for which the appeal activities were conducted. § 133(c)(2)(B)(i).
B. Mandates on the Federal Government.


(210) Promulgate a regulation to govern the emergency care requirements under the Patients' Bill of Rights Act, including guidance on: (i) application of the terms "emergency medical condition" and "prudent layperson"; (ii) an objective standard or methodology for determining when emergency services must be provided based on the prudent layperson standard; and (iii) a delimitation of the scope of the term "emergency services" setting forth the health care scenarios in which such services may be called for. § 101(a)(2)(A) and (a)(2)(B).

(211) Promulgate a regulation to govern maintenance care and post-stabilization case, including an objective standard for determining when and the degree to which such care is required. § 101.

(212) Promulgate a regulation to govern reimbursement for emergency care, maintenance care and post-stabilization care, including a standard or methodology for calculating reimbursement rates for both participating and nonparticipating providers. § 101(b).


(214) Enforce compliance with the emergency care provisions of section 101 of the Act through administrative adjudication proceedings and judicial review of the same. § 101.

(215) Promulgate a regulation setting forth circumstances in which group plans (and other issuers offering individual coverage in connection with group plans) will and will not required to offer point-of-service options, taking into account: (i) plans offering a choice of coverage through more than one issuer; and (ii) plans offering two or more options that differ significantly with respect to the use of participating providers or the available networks of providers. § 102(a)(2).

(216) Promulgate a regulation to govern the parameters of point-of-service options to be offered under the Patients' Bill of Rights Act, including: (i) how plans and issuers are to delimit which nonparticipating providers can and cannot provide point-of-service coverage; (ii) how to determine the extent of plan or issuer contribution; and (iii) how to
establish premiums for point-of-service coverage. § 102(b) and (c).

(217) Investigate possible violations of the point-of-service provisions of section 102 of the Act. § 102.

(218) Enforce compliance with the point-of-service provisions of section 102 of the Act through administrative adjudication proceedings and judicial review of the same. § 102.

(219) Promulgate a regulation setting forth how plans and issuers can comply with the choice of provider provisions of section 103, including: (i) what constitute "appropriate referral procedures"; (ii) how to determine specialty physician availability; and (iii) the circumstances under which the choice of provider requirement does not apply because the plan or issuer has informed participants, beneficiaries or enrollees of limitations on the choice of participating providers. § 103.

(220) Investigate possible violations of the choice-of-provider provisions of section 103 of the Act. § 103.

(221) Enforce compliance with the choice-of-provider provisions of section 103 of the Act through administrative adjudication proceedings and judicial review of the same. § 103.

(222) Promulgate a regulation setting forth how plans and issuers can comply with the specialty care provisions of the Patients' Bill of Rights Act, including: (i) model policy language regarding obstetrical and gynecological care; (ii) an objective standard or methodology for determining when a specialist is called for and defining the term "specialist" for purposes of the statute; and (iii) reimbursement of participating and nonparticipating specialists. § 104(b)(1)(B).

(223) Promulgate a regulation setting forth how plans and issuers can comply with the ongoing special condition provisions of the Act, including: (i) a standard for determining which specific situations constitute "ongoing special conditions"; and (ii) model procedures for use by plans and issuers for the granting of standing referrals. § 104(b)(2)(C).

(224) Investigate possible violations of the specialty care provisions of section 104 of the Act. § 104.

(225) Enforce compliance with the specialty care provisions of section 104 of the Act through administrative adjudication proceedings and judicial review of the same. § 104.
(226) Promulgate a regulation to govern continuity-of-care obligations in situations in which a provider is terminated due to failure to meet applicable quality standards or for fraud. § 105(a)(3).

(227) Promulgate a regulation to govern determinations of continuity-of-care "transitional periods," including determination of "reasonable timeliness" for: (i) institutional care scheduled, but not commenced, before provider termination; (ii) pregnancy care; and (iii) terminal illness care. § 105(b).

(228) Promulgate a regulation to govern situations in which the plan participant, beneficiary or enrollee is entitled to continuity-of-care, but the provider does not agree to comply with the terms and conditions set forth in section 105(c). § 105(c).

(229) Investigate possible violations of the continuity of care provisions of section 105 of the Act. § 105.

(230) Enforce compliance with the continuity of care provisions of section 105 of the Act through administrative adjudication proceedings and judicial review of the same. § 105.

(231) Promulgate a regulation to enable the determination of: (i) which costs in connection with clinical trials are coverable "routine patient costs"; (ii) which costs are not coverable, because they are for "tests or measurements conducted primarily for the purpose of the clinical trial"; and (iii) payment rates for clinical trial services furnished by both participating and nonparticipating providers. § 106(a)(1), (a)(2) and (c).

(232) Promulgate a regulation to enable the identification of "qualified individuals" for clinical trials, including: (i) which illnesses are life-threatening or serious and lacking in an effective standard treatment; (ii) eligibility for trial protocols; and (iii) which trials offer meaningful potential for significant clinical benefit. § 106(b)(1).

(233) Promulgate a regulation to enable the determination or identification of "approved clinical trials," especially those not sponsored by NIH (e.g., clinical trials sponsored by DOD and VA). § 106(d).

(234) Investigate possible violations of the clinical trial provisions of section 106 of the Act. § 106.

(235) Enforce compliance with the clinical trial provisions of section 106 of the Act through administrative adjudication proceedings and judicial review.
of the same. § 106.

(236) Promulgate a regulation setting forth standards for compliance with the prescription drug requirements of the Act, including: (i) physician participation in the development of formularies; (ii) notice to patients; (iii) special coverage requirements. § 107.


(238) Enforce compliance with the prescription drug coverage provisions of section 107 of the Act through administrative adjudication proceedings and judicial review of the same. § 107.

(239) Promulgate a regulation setting forth how plans and issuers can comply with the network adequacy provisions of the Act, including: (i) an objective methodology/standard for achieving and measuring the sufficiency of the number, distribution and variety of providers; and (ii) inclusion of Federally qualified health centers, rural health clinics, migrant health centers, and other essential community providers in specific networks. § 108.


(241) Enforce compliance with the network adequacy provisions of section 108 of the Act through administrative adjudication proceedings and judicial review of the same. § 108.

(242) Promulgate regulatory guidelines for plans and issuers to use in ensuring avoidance of discrimination in the delivery of health care services based on race, color, ethnicity, national origin, religion, sex, age, mental or physical disability, sexual orientation, genetic information or source of payment. Include in such guidance permissible types of considerations (such as pre-existing condition exclusions) that are permissible for eligibility and premium purposes. § 109(b).


(244) Enforce compliance with the patient nondiscrimination provisions of section 109 of the Act through administrative adjudication proceedings and judicial review of the same. § 109.
(245) Promulgate a regulation to implement the quality assurance program requirements of the Act, including: (i) specific compliance standards; and (ii) national accreditation organizations whose accreditations will suffice to demonstrate compliance with such compliance standards. § 111(c)(2).

(246) Promulgate a regulation establishing variations in the quality assurance program requirements of section 111(b) for group plans to take into account differences in the delivery system among group plans and issuers. § 111(d).

(247) Investigate possible violations of the internal quality assurance program provisions of section 111 of the Act. § 111.

(248) Enforce compliance with the internal quality assurance program provisions of section 111 of the Act through administrative adjudication proceedings and judicial review of the same.

(249) Promulgate a regulation specifying the data required to be included in the minimum uniform data set under section 112(a). § 112(b).

(250) Promulgate a regulation to govern the provision of uniform data set data to HHS. § 112(c).

(251) Promulgate a regulation permitting variances in the uniform data set requirements to group plans and issuers to take into account differences in the delivery systems among such plans and issuers. § 112(d).

(252) Investigate possible violations of the standardized data collection provisions of section 112 of the Act. § 112.

(253) Enforce compliance with the standardized data collection provisions of section 112 of the Act through administrative adjudication proceedings and judicial review of the same. § 112.

(254) Promulgate regulatory guidance as to how a plan or issuer can balance its legitimate provider-selection requirements (such as plan population, coverage and quality control requirements) with the prohibition against discrimination based on license or certification. § 113(d)(2).

(255) Promulgate definitions, rules and regulations to carry out the nondiscrimination-in-provider-selection provision of section 113(e). § 113(e)(2).
(256) Investigate possible violations of the provider selection provisions of section 113 of the Act. § 113.

(257) Enforce compliance with the provider selection provisions of section 113 of the Act through administrative adjudication proceedings and judicial review of the same. § 113.

(258) Promulgate regulatory guidance for plans and issuers to use in establishing drug utilization programs. § 114.

(259) Investigate possible violations of the drug utilization review provisions of section 114 of the Act. § 114.

(260) Enforce compliance with the drug utilization review provisions of section 114 of the Act through administrative adjudication proceedings and judicial review of the same.

(261) Promulgate a regulatory definition of the term "utilization review," setting forth multiple decision making points which will be deemed to constitute "utilization review." § 115(a)(3).

(262) Promulgate model utilization review criteria for use by plans and issuers, the adoption of which will demonstrate compliance with section 115. § 115(b)(2)(A).

(263) Promulgate a regulation setting forth for each type of utilization review decision, for each medical category, the type of professionals and training required as a prerequisite to performing such utilization review activities. § 115(c)(2).

(264) Investigate possible violations of the utilization review provisions of section 115 of the Act. § 115.

(265) Enforce compliance with the utilization review provisions of section 115 of the Act through administrative adjudication proceedings and judicial review of the same. § 115.

(266) In serving on the Health Care Quality Advisory Board, consult with the Secretaries responsible for other Federal health insurance and health care programs. § 116(e).

(267) Provide administrative support, scientific support and technical assistance to the Health Care Quality Advisory Board. § 116(f).
Promulgate a regulation setting forth the functions and obligations of the Health Care Quality Advisory Board, including the role the Board will play in specified Federal Government oversight activities under the Act. § 116.

Promulgate a regulation setting forth how health insurance issuers offering non-group coverage must calculate loss ratios for inclusion in informational materials for enrollees. § 121(b)(6).

Promulgate a regulation (after consultation with relevant State authorities) establishing uniform, national reporting standards for the disclosure to all participants, beneficiaries, enrollees and regulatory authorities of the information required to be disclosed under section 121. § 121(d)(1).

Promulgate a regulation specifying the time periods within which plans and issuers must update the information provided to participants, beneficiaries and enrollees on participating providers. § 121(d)(3).

Investigate possible violations of the patient information provisions of section 121 of the Act. § 121.

Enforce compliance with the patient information provisions of section 121 of the Act through administrative adjudication proceedings and judicial review of the same. § 121.

Promulgate a regulation establishing the parameters for plan and issuer procedures designed to protect patient confidentiality. § 122.

Investigate possible violations of the patient confidentiality protection provisions of section 122 of the Act. § 122.

Enforce compliance with the patient confidentiality protection provisions of section 122 of the Act through administrative adjudication proceedings and judicial review of the same. § 122.

In States that do not create and operate a Health Insurance Ombudsman, provide for the creation of such an Ombudsman through a contract with a not-for-profit organization that operates independent of group health plans and health insurance issuers. § 123(b).

Establish a grant program to administer grants to States to establish Health Insurance Ombudsmen through not-for-profit organizations. § 123(c).
Administer the grant program to enable States to establish Health Insurance Ombudsmen through not-for-profit organizations. § 123(c).

Promulgate a regulation setting forth: (i) duties of Health Insurance Ombudsmen; and (ii) plan and issuer notification requirements regarding the availability to patients of the Ombudsmen program. § 123.

Promulgate a regulation setting forth the comprehensive requirements for grievance processes to be established and maintained by plans and issuers. § 131.

Investigate possible violations of the grievance procedures provisions of section 131 of the Act. § 131.

Enforce compliance with the grievance procedures provisions of section 131 of the Act through administrative adjudication proceedings and judicial review of the same. § 131.

Promulgate a regulation setting forth a method for determining the "medical exigencies" of specific health care scenarios, and the time frameworks for resolving expedited internal appeals in connection with each scenario. § 132(b)(3)(A).

Promulgate a regulation setting forth what kinds of health care scenarios require "expedited review." As part of the regulation, establish the specific health care scenarios in which "application of the normal timeframe for making [an internal appeal] determination could seriously jeopardize the life or health of the participant, beneficiary, or enrollee or such an individual’s ability to regain maximum function." § 132(c)(1).

Investigate possible violations of the internal appeals provisions of section 132 of the Act. § 132.

Enforce compliance with the internal appeals provisions of section 132 of the Act through administrative adjudication proceedings and judicial review of the same. § 132.

With respect to group health plans within the separate jurisdictions of HHS and DOL, determine whether to require certification by the Department of "qualified external appeal entities" so as to assure unbiased determinations by such entities. If the Department(s) assume(s) such responsibility, conduct certification of qualified external
appeal entities operating in the Medicare+Choice market. § 133(b)(1)(B)(ii) and (c)(2)(A)(ii).

(289) To the extent that more than one "qualified external appeal entity" is certified to operate in a given market (e.g., group, individual), ensure that: (i) the selection of an entity by a plan or issuer will not create incentives for that entity to make decisions in a biased manner; and (ii) procedures are implemented for auditing a sample of decisions by the qualified external appeal entities to assure that no decisions are made in a biased manner. § 133(b)(1)(B)(iii).

(290) Promulgate standards to govern the elements of the external appeal process with respect to external appeals by participants, beneficiaries and enrollees of plans or issuers subject to Federal oversight. § 133(b)(2).

(291) Promulgate standards to govern the re-certification of "qualified external appeal entities" subject to Federal oversight. § 133(c)(2)(B).

(292) Undertake periodic re-certification of "qualified external appeal entities" subject to Federal oversight. § 133(c)(2)(B).

(293) Investigate possible violations of the external appeals provisions of section 133 of the Act. § 133.

(294) Enforce compliance with the external appeals provisions of section 133 of the Act through administrative adjudication proceedings and judicial review of the same. § 133.

(295) Promulgate a regulation setting forth what types of communications between a provider and a patient constitute "medical communications" for all of the health care delivery scenarios subject to the prohibition of interference with such medical communications. § 141(c)(1).

(296) Promulgate a regulation setting forth what types of statements made by a provider to a patient will be deemed "knowing or willful misrepresentation." § 141(c)(2).

(297) Promulgate a regulation setting forth what types of quality improvement and effective utilization provisions in plan/issuer-provider agreements do and do not violate the prohibition against restricting provider-patient medical communications. § 141(b)(1).

(298) Promulgate a regulation setting forth what types of provider-patient
communications constitute misrepresentations regarding the scope of benefits or the availability of reimbursement from a plan or issuer. § 141(b)(2).

(299) Promulgate model language for adoption by plans and issuers for insertion into contracts with providers specifying what kinds of communications are and are not permitted. § 141.

(300) Investigate possible violations of the prohibition against restraints on medical communications of section 141 of the Act. § 141.

(301) Enforce compliance with the prohibition against restraints on medical communications of section 141 of the Act through administrative adjudication proceedings and judicial review of the same. § 141.

(302) Promulgate a regulation governing physician incentive plans including the following elements: (i) definition of “incentive plan”; (ii) parameters of valid and invalid provisions for such plans; and (iii) procedures for review and approval/disapproval of contract language including incentive plans. § 142.

(303) Monitor physician incentive plans for compliance with section 1876(i)(8) of the Social Security Act, as incorporated by reference into the Patients’ Bill of Rights Act. In particular, determine: (i) whether incentive plans or arrangements provide for specific payments to be made directly or indirectly to physicians or physician groups as an inducement to reduce or limit medically necessary services provided to patients; (ii) whether the health plan or issuer has provided stop-loss protection for the physicians or physician groups; (iii) whether the health plan or issuer has conducted periodic surveys of patient access and satisfaction; and (iv) whether the health plan or issuer has provided HHS or DOL with descriptive information sufficient to enable the HHS or DOL to determine whether the incentive plan/arrangement is lawful. § 142(b)(2), incorporating by reference § 1876(i)(8) of the Social Security Act.

(304) Investigate possible violations of the physician incentive limitations of section 142 of the Act. § 142.

(305) Enforce compliance with the physician incentive limitations of section 142 of the Act through administrative adjudication proceedings and judicial review of the same. § 142.

(306) Promulgate a regulation setting forth the compliance obligations of
plans and issuers with respect to: (i) provider credentialing procedures; (ii) adverse credentialing decisions; and (iii) provider input in developing credentialing procedures. § 143.

(307) Investigate possible violations of the provider credentialing provisions of section 143 of the Act. § 143.

(308) Enforce compliance with the provider credentialing provisions of section 143 of the Act through administrative adjudication proceedings and judicial review of the same. § 143.

(309) Promulgate a regulation setting forth how to determine the specific types of disclosures, by "protected health care professionals" and "institutional providers," that are protected from retaliation by plans or issuers. § 144(b)(1).

(310) Promulgate a regulation setting forth what factors must be present in order for a health care professional or institutional provider to be deemed a "protected health care professional" or "protected institutional health care provider" for purposes of the patient advocacy protection provisions of the Patients' Bill of Rights Act. The regulation should address when employees or a provider are under a duty to address patient-related concerns to their superiors within the physician group or institutional provider before making disclosures to patients. § 144(b)(7).

(311) Promulgate a regulation setting forth an objective methodology or set of factors for determining when a "protected health care professional" or "institutional provider" is "acting in good faith" in disclosing information to "appropriate" outside parties regarding care, services or conditions affecting one or more patients. The regulation should include methods for determining: (i) the degree of learning and skill ordinarily possessed by specific types of health care professionals in order to make specific types of disclosures; (ii) what constitutes "reasonable belief that given 'information' is true"; (iii) the extent to which specific types of providers would be required to comply with specific types of plan/issuer procedures before making disclosures to patients, taking into account the possibility of imminent dangers to patients. § 144(b)(2).

(312) Promulgate a regulation setting forth: (i) specific types of disclosures that would violate Federal or State law or would diminish or impair the rights of any person to the continued protection of confidentiality of communications provided by such law; (ii) which types of disclosures are not protected by the patient advocacy protection provisions of the
Patients' Bill of Rights Act. § 144(b)(3)(A).

(313) Promulgate a regulation setting forth the plan/issuer internal procedures with which protected health care professionals and institutional providers are and are not required to comply with, in order to be protected by the patient advocacy protection provisions of the Patients' Bill of Rights Act, taking into account: (i) degree of notice of such internal provisions; (ii) inherent statutory and regulatory validity of such internal provisions; (iii) imminence of harm to the patient who is the subject of the disclosure; and (iv) exceptions for required disclosures to, and investigations by, appropriate regulatory bodies. § 144(b)(3).

(314) Promulgate a regulation setting forth an objective standard for determining when a plan or issuer is entitled to take adverse action against a protected health care professional or institutional provider based on a showing that the plan or issuer would have taken such adverse action even in the absence of otherwise protected disclosures made by the professional or provider. § 144(b)(4).

(315) Promulgate a regulation setting forth what a plan or issuer must do to demonstrate that a nonpayment or nonreimbursement decision is not a form of retaliation against a professional or provider for engaging in "patient advocacy." § 144(b)(6)(A).

(316) Promulgate a regulation setting forth what types of provisions in peer review or utilization review protocols or internal quality procedures do and do not violate the "patient advocacy provisions" of the Patients' Bill of Rights Act. § 144(b)(6)(B).

(317) Investigate possible violations of the patient advocacy protection provisions of section 144 of the Act. § 144.

(318) Enforce compliance with the patient advocacy protection provisions of section 144 of the Act through administrative adjudication proceedings and judicial review of the same. § 144.

(319) Promulgate a standard for determining when a plan or issuer is arbitrarily interfering with or altering the decision of a treating physician regarding the manner or setting within which particular services are delivered, addressing in particular: (i) the different types of medical scenarios in which these determinations will have to be made; (ii) what constitutes "arbitrary"; (iii) what constitutes "medically necessary"; (iv) equally viable treatment or diagnosis options; and (v) the
role of valid utilization review, quality and coverage limitations. § 151.

(320) Investigate possible violations of the good medical practice provisions of section 151 of the Act. § 151.

(321) Enforce compliance with the good medical practice provisions of section 151 of the Act through administrative adjudication proceedings and judicial review of the same. § 151.

(322) Promulgate a regulation setting forth guidelines for establishing breast cancer coverages in conformance with section 152. Include in the regulation guidelines for: (i) establishing appropriate hospital stay limitations; (ii) avoiding terms and conditions that constitute monetary or other incentives to induce noncompliance; (iii) establishing deductibles, coinsurance and other cost-sharing provisions that do not violate section 152; and (iv) the relationship between the new Federal requirements and existing State laws. § 152.

(323) Investigate possible violations of the breast cancer treatment provisions of section 152 of the Act. § 152.

(324) Enforce compliance with the breast cancer treatment provisions of section 152 of the Act through administrative adjudication proceedings and judicial review of the same. § 152.

(325) Promulgate a regulation setting forth guidelines for establishing reconstructive breast surgery coverages in conformance with section 153. Include in the regulation guidelines for: (i) negotiation of provider reimbursement levels for reconstructive breast surgery; (ii) appropriate hospital stay limitations; (iii) avoiding terms and conditions that constitute monetary or other incentives to induce noncompliance; (iv) establishing deductibles, coinsurance and other cost-sharing provisions that do not violate section 153; and (v) the relationship between the new Federal requirements and existing State laws. § 153.

(326) Investigate possible violations of the reconstructive breast surgery provisions of the Act. § 153.

(327) Enforce compliance with the reconstructive breast surgery provisions of the Act through administrative adjudication proceedings and judicial review of the same. § 153.

(328) Promulgate regulatory guidance setting forth which types of State-law provisions pertaining to group health insurance are and are not
preempted by the Patients’ Bill of Rights Act. § 192(a) and (c).

2. **Additional, ERISA-Related Mandates on the Department of Labor.**

(329) Promulgate a regulation setting forth the circumstances under which a group plan providing benefits in the form of coverage through an issuer would not be required to comply with the patient information requirements of section 121, provided that the issuer complied with the requirements. § 301(a), adding new § 713(b)(2) to ERISA.

(330) Promulgate a regulation setting forth the circumstances under which a group plan providing benefits in the form of coverage through an issuer would not be required to comply with the grievance and internal appeals requirements of sections 131 and 132, provided that the issuer complied with the requirements. § 301(a), adding new § 713(b)(3) to ERISA.

(331) Promulgate a regulation setting forth the circumstances under which a group plan could contract with a qualified external appeal entity for the conduct of external appeal activities in accordance with section 133, and thereby be insulated from liability for any violations of section 133 committed by the entity. § 301(a), adding new § 713(b)(4) to ERISA.

(332) Promulgate a regulation setting forth circumstances under which a group plan would not be deemed liable for violations of section 109, 141, 142, 144 or 151 of the Patients’ Bill of Rights Act so long as the group plan did not actually cause the violation. § 301(a), adding new § 713(b)(5) to ERISA.

(333) Investigate complaints filed by health care professionals alleging retaliation or discrimination in violation of section 144(b)(1) of the Patients’ Bill of Rights Act. § 301(a), adding new § 713(c) to ERISA.

(334) Conduct administrative adjudications of colorable claims of health care professionals alleging retaliation or discrimination in violation of section 144(b)(1) of the Patients’ Bill of Rights Act. When appropriate, issue orders to ensure that the protected health care professional do not suffer any losses of position, pay or benefits. § 301(a), adding new § 713(c) to ERISA.

(335) Promulgate a regulation coordinating provisions of the Patients’ Bill of Rights Act applicable to ERISA plans with other ERISA statutory and regulatory requirements. § 301(a), adding new § 713(d) to ERISA.
3. **Mandates on the Department of the Treasury.**

In coordination with the Departments of HHS and Labor, monitor compliance of group plans with the substantive provisions of the Patients' Bill of Rights Act, and revoke group plan status of noncomplying plans for purposes of Subchapter B of Chapter 100 of the Internal Revenue Code. § 401.

4. **Mandates on the President and Congress.**

a. **Mandates on the President.**

Establish the Health Care Quality Advisory Board as a vehicle to provide information to Congress and the Administration on issues relating to quality monitoring and improvement in the health care provided under group health plans and health insurance coverage. § 116(a).

Appoint 20 members to the Health Care Quality Advisory Board (in addition to the Secretaries of HHS and Labor). § 116(b).

b. **Mandates on Congress.**

Consult with the President in appointing members to the Health Care Quality Advisory Board. § 116(b).
5. **Mandates on the Health Care Quality Advisory Board.**

(340) Provide information to Congress and the Administration on issues relating to quality monitoring and improvement in the health care provided under group health plans and health insurance coverage. § 116(a).

(341) Identify, update and disseminate measures of health care quality for group plans and issuers, including both network and non-network plans. § 116(c)(1).

(342) Advise the Secretary of HHS on the development and maintenance of the minimum data set developed pursuant to section 112(b). § 116(c)(2).

(343) Advise the Secretary of HHS on standardized formats for information on group health plans and individual health insurance coverage. § 116(c)(3).

(344) In identifying health care quality measures pursuant to section 116(c)(1), consult with national health care standard setting bodies which define quality indicators, the Agency for Health Care Policy and Research, the Institute of Medicine and other public and private entities with expertise in health care quality. § 116(c).

(345) Provide an annual report to Congress and the President on the quality of health care in the U.S. and national and regional trends in health care quality. Include in the report a description of determinants of health care quality and measurements of practice and quality variability within the U.S. § 116(d).
6. Mandates on the Agency for Health Care Policy and Research (Within the Public Health Service).

(346) Assist the Health Care Quality Advisory Board in identifying health care quality measures. § 116(c).

7. Mandates on Health Care Ombudsmen (to Be Paid for Through Federal Funding).

(347) Assist consumers within the ombudsman's particular State in choosing among health insurance coverage or among coverage options offered within group plans. § 123(a)(1).

(348) Provide counseling and assistance to enrollees in connection with: (i) dissatisfaction with their treatment by plans or issuers; and (ii) grievances and appeals. § 123(a)(2).
C. Mandates on State Governments.

(349) Assist the Secretary of HHS in developing a regulation establishing uniform, national reporting standards for the disclosure to all participants, beneficiaries, enrollees and regulatory authorities of the information required to be disclosed under section 121. § 121(d)(1).

(350) Create and operate a Health Insurance Ombudsman through a contract with a not-for-profit organization that operates independent of group health plans and health insurance issuers. § 123(a).

(351) Determine whether to require State certification of "qualified external appeal entities" so as to assure unbiased determinations by such entities. If the State assumes this responsibility, conduct certification of qualified external appeal entities operating in the State. § 133(b)(1)(B)(i) and (c)(2)(A)(ii).

(352) To the extent that more than one "qualified external appeal entity" is certified to operate in the State, ensure that: (i) the selection of an entity by a plan or issuer will not create incentives for that entity to make decisions in a biased manner; and (ii) procedures are implemented for auditing a sample of decisions by the qualified external appeal entities to assure that no decisions are made in a biased manner. § 133(b)(1)(B)(iii).

(353) Promulgate standards to govern the elements of the external appeal process with respect to external appeals by participants, beneficiaries and enrollees of plans or issuers subject to State oversight. § 133(b)(2).

(354) Promulgate standards to govern the re-certification of "qualified external appeal entities" subject to State oversight. § 133(c)(2)(B).

(355) Undertake periodic re-certification of "qualified external appeal entities" subject to State oversight. § 133(c)(2)(B).

(356) Promulgate a regulation governing physician incentive plans including the following elements: (i) definition of "incentive plan"; (ii) parameters of valid and invalid provisions for such plans; and (iii) procedures for review and approval/disapproval of contract language including incentive plans. § 142.
Monitor physician incentive plans for compliance with section 1876(i)(8) of the Social Security Act, as incorporated by reference into the Patients' Bill of Rights Act. In particular, determine: (i) whether incentive plans or arrangements provide for specific payments to be made directly or indirectly to physicians or physician groups as an inducement to reduce or limit medically necessary services provided to patients; (ii) whether the health plan or issuer has provided stop-loss protection for the physicians or physician groups; (iii) whether the health plan or issuer has conducted periodic surveys of patient access and satisfaction; and (iv) whether the health plan or issuer has provided the State with descriptive information sufficient to enable the State to determine whether the incentive plan/arrangement is lawful. § 142(b)(2), incorporating by reference § 1876(i)(8) of the Social Security Act.

Investigate possible violations of Title I of the Patients' Bill of Rights Act by plans or issuers subject to State law. §§ 101-153.

Enforce compliance with Title I of the Patients' Bill of Rights Act by plans or issuers subject to State law through administrative adjudication proceedings. §§ 101-153.
Chapter Two
New Causes of Action Under the Patients' Bill of Rights Act

(1) Claims that plans or issuers failed to provide emergency services without requiring prior authorization in specific instances. § 101(a)(1)(A).

(2) Claims that plans or issuers failed to provide reimbursement to nonparticipating providers for emergency services in specific instances. § 101(a)(1)(B).

(3) Claims of violations of the requirement that the participant, beneficiary or enrollee not be charged for amounts charged by a nonparticipating provider furnishing emergency care, maintenance care or post-stabilization care that exceed what a participating provider would have charged. § 101(a)(1)(C)(i) and (b).

(4) Claims of violations of the requirement that the plan pay a nonparticipating provider furnishing emergency care, maintenance care or post-stabilization care more than his or her normal fee when that fee is lower than what a participating provider would have charged. § 101(a)(1)(C)(ii) and (b).

(5) Disputes over alleged violations of the requirement that emergency services be paid without regard to other coverage terms or conditions. § 101(a)(1)(D).

(6) Claims that plans or issuers failed to authorize or reimburse for emergency services in violation of the "prudent layperson" standard in specific instances. § 101(a)(2)(A).

(7) Claims that plans or issuers failed to offer group network plan participants the option to purchase point-of-service coverage for all benefits otherwise limited to coverage through the network (or, failed to offer such option at the statutorily mandated time). § 102(a)(1).

(8) Claims that plans or issuers failed to enable a participants, beneficiaries or enrollees to receive primary care from the participating primary care providers of their choice, including disputes regarding the availability of such providers of choice. § 103(a).
Claims that plans or issuers failed to provide adequate access to specialty care, including violation of appropriate procedures mandating referral to the specialist of the participant's, beneficiary's or enrollee's choice. §§ 103(b)(1) and 104(b)(1)(A).

Claims that plans or issuers failed to permit female participants, beneficiaries or enrollees to designate participating physicians who specializes in obstetrics and gynecology to be their primary care providers. § 104(a)(1)(A).

Disputes concerning alleged violations of the provision that a female participant, beneficiary or enrollee who has not designated an obstetrician or gynecologist as her primary care provider need not obtain authorization or referral by her primary care provider for coverage of routine gynecological care (such as preventive women’s health examinations) and pregnancy-related services provided by a participating obstetrician or gynecologist. § 104(a)(1)(B)(i).

Disputes concerning alleged violations of the statutory and implementing regulatory requirements pertaining to the development of treatment plans for specialty care. §§ 104(b)(1)(C)(i) and (ii).

Disputes concerning alleged failures to provide adequate access to nonparticipating specialists, including disputes of availability and accessibility of participating and nonparticipating specialists in specific cases. § 104(b)(1)(D).

Claims that plans or issuers violated the requirement that participants, beneficiaries or enrollees not be charged for amounts charged by nonparticipating specialists that exceed what participating providers would have charged. § 104(b)(1)(E).

Disputes concerning alleged failures to comply with the ongoing care provisions of section 104, including disputes over failure to provide desired referrals for ongoing care, disputes over the existence of "ongoing special conditions" in specific instances, disputes regarding oversight by nonspecialist primary care providers for quality assurance purposes, and challenges to plans' procedures for such ongoing referrals. § 104(b) and (c).

Disputes concerning alleged failures to comply with the continuity of care provisions of section 105, including disputes over the adequacy of notices, disputes over the duration of the continued care provided and disputes over reimbursement for continued care. § 105(a) and (b).
Disputes over alleged violations of the clinical research coverage provisions of section 106, including disputes over the appropriateness of patient participation in specific instances, disputes over reimbursement for routine and non-routine costs associated with the participation, and allegations of discrimination based on participation in clinical trials. § 106(a).

Challenges to refusals by plans or issuers to authorize or reimburse for specific drugs on the grounds that the plan or issuer failed to allow providers adequate participation in the process of developing the formulary, on the grounds that the plan or issuer failed to provide adequate notice of formulary restrictions in specific instances, or on the grounds that an exception should be provided. § 107(a)(1), (a)(2) and (a)(3).

Challenges to decisions by plans or issuers not to authorize or reimburse for drugs or medical devices still under post-marketing scrutiny by the Food and Drug Administration. § 107(b)(1)(A)(i) and (b)(1)(B).

Challenges to the adequacy of specific plan networks, including challenges in which patients act as "straw men" for disgruntled providers who are denied participation for lawful reasons. § 108(a).

Discrimination claims based on allegations of disparate impact with respect to race, color, ethnicity, national origin, religion, sex, age, mental or physical disability, sexual orientation, genetic information or source of payment. § 109(a).

Claims that specific decisions of a plan or issuer violate the plan's or issuer's quality assurance plan. § 111.

Challenges to specific provisions or adequacy of a plan's or issuer's quality assurance plan. § 111.

Claims that specific misadventures could have been avoided had the quality assurance program been drafted or followed differently. § 111.

Challenges by providers to the written procedures for the credentialing of health care professionals. § 113(a).

Challenges by providers to adverse credentialing decisions, including claims of discrimination based on race, color, religion, sex, national origin, age, sexual orientation, disability or high-risk patient base. 113(e)(1).
Challenges to utilization review decisions on the grounds that the plan or issuer did not comply with the plan’s written utilization review program. § 115(a)(1) and (b)(1).

Challenges to specific utilization review plans on the grounds that providers were not given adequate input into developing the plan, and on the grounds that the needs of at-risk populations, patients with chronic conditions/serious illnesses and pediatric patients were not adequately taken into account. § 115(b)(2) and (b)(4).

Challenges to reversals of prior authorizations based on new information or developments. § 115(b)(2)(B).

Challenges to utilization review decisions on the grounds that the medical decisionmakers were not "clinical peers." § 115(c)(2)(B).

Claims that a plan or issuer is providing compensation to its employees, agents or contractors in a manner that provides incentives for such persons to make inappropriate or adverse review decisions. § 115(c)(2)(C).

Challenges to the frequency with which a plan or issuer requires utilization review in specific instances, including disputes over whether such frequency is justified by quality assurance considerations. § 115(c)(4).

Disputes over whether a plan or issuer is entitled to specific types of information in connection with specific utilization review activities. § 115(c)(5).

Disputes over the frequency and degree of access to the plan’s or issuer’s medical director to discuss adverse utilization review decisions. § 115(c)(6).

Challenges to the adequacy of information provided or made available pursuant to section 121. § 121.

Disputes over whether information packages are required to be provided in languages other than English, including disputes over the percentage of specific foreign language speakers in specific geographical areas, and disputes over how such geographical areas are to be determined, as well as claims of discrimination in connection with the same. § 121(b)(3)(H).
(37) Challenges to the adequacy of disclosures by plans and issuers of their methods of compensating participating physicians, including disputes over the extent to which such information constitutes protected trade secrets. § 121(c)(3).

(38) Challenges to alleged violations of patient privacy safeguards, especially in connection with statistical disclosures mandated by the Act. § 122.

(39) Challenges to the adequacy of procedures established by plans and issuers to safeguard privacy of any individually identifiable enrollee information. § 122(1).

(40) Claims that plans or issuers did not provide adequate timely access to patient information. § 122(3).

(41) Challenges to the adequacy of the internal grievance procedures established by plans or issuers. § 131(a) and (b).

(42) Claims that a plan's or issuer's internal grievance procedures were not adequately or timely followed in specific instances. § 131(b).

(43) Challenges to the adequacy of the internal appeal procedures established by plans or issuers. § 132.

(44) Claims that a plan's or issuer's internal appeal procedures were not adequately or timely followed in specific instances, including challenges to the medical personnel selected by the plan or issuer to conduct the appeal. § 132.

(45) Claims that specific appeals should have been granted expedited appeal status. § 132(c).

(46) Challenges to the adequacy of the external appeal procedures established by plans or issuers. § 133.

(47) Claims that a plan's or issuer's external appeal procedures were not adequately or timely followed in specific instances. § 133.

(48) Claims of "negligent hiring or selection" of qualified external appeal entities. § 133(b).

(49) Challenges to the adequacy of access granted to plan or issuer records in connection with external appeals. § 133(b)(2)(D).
Claims that the provisions of contracts or agreements between the plan or issuer and a health care provider prohibit or restrict the provider from engaging in medical communications with the provider's patient. § 141(a)(1).

Challenges to the provisions of contracts or agreements between the plan or issuer and a health care provider on the grounds that they purport to transfer to the provider, by indemnification or otherwise, liability relating to activities, actions or omissions of the plan, the issuer or an agent of the plan or issuer (as opposed to activities, actions or omissions of the provider). § 142(a)(1).

Challenges to provisions of contracts or agreements between the plan or issuer and a health care provider on the grounds that such provisions constitute unlawful physician incentive plans. § 142(b)(1).

Claims that a plan or issuer is retaliating against a participant, beneficiary, enrollee or provider based on the participant's, beneficiary's, enrollee's or provider's use of or participation in a utilization review process or grievance process of the plan or issuer (including an internal or external review or appeal process) under the Act. § 144(a).

Challenges to the adequacy of procedures established by the plan or issuer to ensure that the plan or issuer does not arbitrarily interfere with or alter the decision of a treating physician regarding the manner or setting within which particular services are delivered if the services are medically necessary or appropriate for treatment or diagnosis, or to the extent that treatment is otherwise a covered benefit. § 151(a)(1).

Claims that the plan or issuer has violated the "good medical practice" procedures established by the plan or issuer pursuant to section 151. § 151.

Claims that treatment for breast cancer or reconstructive breast surgery was improperly denied in specific instances. §§ 152 and 153.
Chapter Three
New Federal Regulations Required to Implement the Patients’ Bill of Rights Act

(1) Emergency care requirements under the Patients’ Bill of Rights Act, including guidance on: (i) application of the terms “emergency medical condition” and “prudent layperson”; (ii) an objective standard or methodology for determining when emergency services must be provided based on the prudent layperson standard; and (iii) a delimitation of the scope of the term “emergency services” setting forth the health care scenarios in which such services may be called for. § 101(a)(2)(A) and (a)(2)(B).

(2) Maintenance care and post-stabilization care required under the Act, including an objective standard for determining when and the degree to which such care is required. § 101.

(3) Reimbursement requirements for emergency care, maintenance care and post-stabilization care, including a standard or methodology for calculating reimbursement rates for both participating and nonparticipating providers. § 101(b).

(4) Circumstances in which group plans (and other issuers offering individual coverage in connection with group plans) will and will not be required to offer point-of-service options, taking into account: (i) plans offering a choice of coverage through more than one issuer; and (ii) plans offering two or more options that differ significantly with respect to the use of participating providers or the available networks of providers. § 102(a)(2).

(5) Parameters of point-of-service options to be offered under the Patients’ Bill of Rights Act, including: (i) how plans and issuers are to delimit which nonparticipating providers can and cannot provide point-of-service coverage; (ii) how to determine the extent of plan or issuer contribution; and (iii) how to establish premiums for point-of-service coverage. § 102(b) and (c).

(6) Standard for compliance by plans and issuers with the choice of provider provisions of section 103, including: (i) what constitute “appropriate referral procedures”; (ii) how to determine specialty physician availability; and (iii) the circumstances under which the choice of provider requirement does not apply because the plan or issuer has
informed participants, beneficiaries or enrollees of limitations on the choice of participating providers. § 103.

(7) Standard for compliance by plans and issuers with the specialty care provisions of the Act, including: (i) model policy language regarding obstetrical and gynecological care; (ii) an objective standard or methodology for determining when a specialist is called for and defining the term "specialist" for purposes of the statute; and (iii) reimbursement of participating and nonparticipating specialists. § 104(b)(1)(B).

(8) Standard for compliance by plans and issuers with the ongoing special condition provisions of the Act, including: (i) a standard for determining which specific situations constitute "ongoing special conditions"; and (ii) model procedures for use by plans and issuers for the granting of standing referrals. § 104(b)(2)(C).

(9) Continuity-of-care obligations in situations in which a provider is terminated due to failure to meet applicable quality standards or for fraud. § 105(a)(3).

(10) Determinations of continuity-of-care "transitional periods," including determination of "reasonable timeliness" for: (i) institutional care scheduled, but not commenced, before provider termination; (ii) pregnancy care; and (iii) terminal illness care. § 105(b).

(11) Entitlement to continuity of care when the provider does not agree to comply with the terms and conditions set forth in section 105(c). § 105(c).

(12) Standard for the determination of: (i) which costs in connection with clinical trials are coverable "routine patient costs"; (ii) which costs are not coverable, because they are for "tests or measurements conducted primarily for the purpose of the clinical trial"; and (iii) payment rates for clinical trial services furnished by both participating and nonparticipating providers. § 106(a)(1), (a)(2) and (c).

(13) Standard to enable the identification of "qualified individuals" for clinical trials, including: (i) which illnesses are life-threatening or serious and lacking in an effective standard treatment; (ii) eligibility for trial protocols; and (iii) which trials offer meaningful potential for significant clinical benefit. § 106(b)(1).

(14) Standard for the determination or identification of "approved clinical trials," especially those not sponsored by NIH (e.g., clinical trials

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sponsored by DOD and VA). § 106(d).

(15) Standards for compliance with the prescription drug requirements of the Act, including: (i) physician participation in the development of formularies; (ii) notice to patients; (iii) special coverage requirements. § 107.

(16) Standard for compliance with the network adequacy provisions of the Act, including: (i) an objective methodology/standard for achieving and measuring the sufficiency of the number, distribution and variety of providers; and (ii) inclusion of Federally qualified health centers, rural health clinics, migrant health centers, and other essential community providers in specific networks. § 108.

(17) Standard for ensuring avoidance of discrimination in the delivery of health care services based on race, color, ethnicity, national origin, religion, sex, age, mental or physical disability, sexual orientation, genetic information or source of payment. Include in such guidance permissible types of considerations (such as pre-existing condition exclusions) that are permissible for eligibility and premium purposes. § 109(b).

(18) Standard for implementation of the quality assurance program requirements of the Act, including: (i) specific compliance standards; and (ii) national accreditation organizations whose accreditations will suffice to demonstrate compliance with such compliance standards. § 111(c)(2).

(19) Standard for establishing variations in the quality assurance program requirements of section 111(b) for group plans to take into account differences in the delivery system among group plans and issuers. § 111(d).

(20) Data required to be included in the minimum uniform data set under section 112(a). § 112(b).

(21) Requirements for the provision of uniform data set data to HHS. § 112(c).

(22) Standard for permitting variances in the uniform data set requirements to group plans and issuers to take into account differences in the delivery systems among such plans and issuers. § 112(d).
Standard for determining how a plan or issuer can balance its legitimate provider-selection requirements (such as plan population, coverage and quality control requirements) with the prohibition against discrimination based on license or certification. § 113(d)(2).

Definitions, rules and regulations to carry out the nondiscrimination-in-provider-selection provision of section 113(e). § 113(e)(2).

Guidance for plans and issuers to use in establishing drug utilization programs. § 114.

Regulatory definition of the term "utilization review," setting forth multiple decision making points which will be deemed to constitute "utilization review." § 115(a)(3).

Model utilization review criteria for use by plans and issuers, the adoption of which will demonstrate compliance with section 115. § 115(b)2(A).

Standard setting forth for each type of utilization review decision, for each medical category, the type of professionals and training required as a prerequisite to performing such utilization review activities. § 115(c)(2).

Standard setting forth the functions and obligations of the Health Care Quality Advisory Board, including the role the Board will play in specified Federal Government oversight activities under the Act. § 116.

Standard setting forth how health insurance issuers offering non-group coverage must calculate loss ratios for inclusion in informational materials for enrollees. § 121(b)(6).

Uniform, national reporting standards for the disclosure to all participants, beneficiaries, enrollees and regulatory authorities of the information required to be disclosed under section 121. § 121(d)(1).

Time periods within which plans and issuers must update the information provided to participants, beneficiaries and enrollees on participating providers. § 121(d)(3).

Parameters for plan and issuer procedures designed to protect patient confidentiality. § 122.
Rules and procedures governing the grant program to administer grants to States to establish Health Insurance Ombudsmen through not-for-profit organizations. § 123(c).

Duties of Health Insurance Ombudsmen and plan/issuer notification requirements regarding the availability to patients of the Ombudsmen program. § 123.

Comprehensive requirements for grievance processes to be established and maintained by plans and issuers. § 131.

Standard for determining the "medical exigencies" of specific health care scenarios, and the time frameworks for resolving expedited internal appeals in connection with each scenario. § 132(b)(3)(A).

Regulation setting forth what kinds of health care scenarios require "expedited review." As part of the regulation, establish the specific health care scenarios in which "application of the normal timeframe for making [an internal appeal] determination could seriously jeopardize the life or health of the participant, beneficiary, or enrollee or such an individual's ability to regain maximum function." § 132(c)(1).

Standard to govern the elements of the external appeal process with respect to external appeals by participants, beneficiaries and enrollees of plans or issuers subject to Federal oversight. § 133(b)(2).

Standards to govern the re-certification of "qualified external appeal entities" subject to Federal oversight. § 133(c)(2)(B).

Types of communications between a provider and a patient constituting "medical communications" for all of the health care delivery scenarios subject to the prohibition against interference with such medical communications. § 141(c)(1).

Types of statements made by a provider to a patient will be deemed "knowing or willful misrepresentation." § 141(c)(2).

Types of quality improvement and effective utilization provisions in plan/issuer-provider agreements do and do not violate the prohibition against restricting provider-patient medical communications. § 141(b)(1).

Types of provider-patient communications constitute misrepresentations regarding the scope of benefits or the availability of reimbursement from
a plan or issuer. § 141(b)(2).

(45) Model language for adoption by plans and issuers for insertion into contracts with providers specifying what kinds of communications are and are not permitted. § 141.

(46) Standard governing physician incentive plans including the following elements: (i) definition of "incentive plan"; (ii) parameters of valid and invalid provisions for such plans; and (iii) procedures for review and approval/disapproval of contract language including incentive plans. § 142.

(47) Standard setting forth the compliance obligations of plans and issuers with respect to: (i) provider credentialing procedures; (ii) adverse credentialing decisions; and (iii) provider input in developing credentialing procedures. § 143.

(48) Regulation setting forth how to determine the specific types of disclosures, by "protected health care professionals" and "institutional providers," that are protected from retaliation by plans or issuers. § 144(b)(1).

(49) Regulation setting forth what factors must be present in order for a health care professional or institutional provider to be deemed a "protected health care professional" or "protected institutional health care provider" for purposes of the patient advocacy protection provisions of the Patients' Bill of Rights Act, including circumstances under which employees or a provider are under a duty to address patient-related concerns to their superiors within the physician group or institutional provider before making disclosures to patients. § 144(b)(7).

(50) Regulation setting forth an objective methodology or set of factors for determining when a "protected health care professional" or "institutional provider" is "acting in good faith" in disclosing information to "appropriate" outside parties regarding care, services or conditions affecting one or more patients, including standards for determining: (i) the degree of learning and skill ordinarily possessed by specific types of health care professionals in order to make specific types of disclosures; (ii) what constitutes "reasonable belief that given 'information' is true"; (iii) the extent to which specific types of providers would be required to comply with specific types of plan/issuer procedures before making disclosures to patients, taking into account the possibility of imminent dangers to patients. § 144(b)(2).
(51) Regulation setting forth: (i) specific types of disclosures that would violate Federal or State law or would diminish or impair the rights of any person to the continued protection of confidentiality of communications provided by such law; (ii) which types of disclosures are not protected by the patient advocacy protection provisions of the Act. § 144(b)(3)(A).

(52) Regulation setting forth the plan/issuer internal procedures with which protected health care professionals and institutional providers are and are not required to comply with, in order to be protected by the patient advocacy protection provisions of the Act, taking into account: (i) degree of notice of such internal provisions; (ii) inherent statutory and regulatory validity of such internal provisions; (iii) imminence of harm to the patient who is the subject of the disclosure; and (iv) exceptions for required disclosures to, and investigations by, appropriate regulatory bodies. § 144(b)(3).

(53) Objective standard for determining when a plan or issuer is entitled to take adverse action against a protected health care professional or institutional provider based on a showing that the plan or issuer would have taken such adverse action even in the absence of otherwise protected disclosures made by the professional or provider. § 144(b)(4).

(54) Standard setting forth what a plan or issuer must do to demonstrate that a nonpayment or nonreimbursement decision is not a form of retaliation against a professional or provider for engaging in "patient advocacy." § 144(b)(6)(A).

(55) Regulation setting forth what types of provisions in peer review or utilization review protocols or internal quality procedures do and do not violate the "patient advocacy provisions" of the Patients' Bill of Rights Act. § 144(b)(6)(B).

(56) Standard for determining when a plan or issuer is arbitrarily interfering with or altering the decision of a treating physician regarding the manner or setting within which particular services are delivered, addressing in particular: (i) the different types of medical scenarios in which these determinations will have to be made; (ii) what constitutes "arbitrary"; (iii) what constitutes "medically necessary"; (iv) equally viable treatment or diagnosis options; and (v) the role of valid utilization review, quality and coverage limitations. § 151.

(57) Regulation setting forth guidelines for establishing breast cancer coverages in conformance with section 152. Include in the regulation
guidelines for: (i) establishing appropriate hospital stay limitations; (ii) avoiding terms and conditions that constitute monetary or other incentives to induce noncompliance; (iii) establishing deductibles, coinsurance and other cost-sharing provisions that do not violate section 152; and (iv) the relationship between the new Federal requirements and existing State laws. § 152.

(58) Regulation setting forth guidelines for establishing reconstructive breast surgery coverages in conformance with section 153. Include in the regulation guidelines for: (i) negotiation of provider reimbursement levels for reconstructive breast surgery; (ii) appropriate hospital stay limitations; (iii) avoiding terms and conditions that constitute monetary or other incentives to induce noncompliance; (iv) establishing deductibles, coinsurance and other cost-sharing provisions that do not violate section 153; and (v) the relationship between the new Federal requirements and existing State laws. § 153.

(59) Guidance setting forth which types of State-law provisions pertaining to group health insurance are and are not preempted by the Patients’ Bill of Rights Act. § 192(a) and (c).
Chapter Four
New Federal Hires and Appropriations

MBS was asked to determine:

- 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 the Patients' Bill of Rights Act?

- What annual Federal appropriations would be required to maintain this staffing level?

MBS's Analysis

Implementation of the Patients' Bill of Rights Act 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>$120,324,688.00</td>
</tr>
<tr>
<td>Administrative Adjudications</td>
<td>724</td>
<td>$ 29,371,232.00</td>
</tr>
<tr>
<td>Appellate Review Units</td>
<td>20</td>
<td>$ 811,360.00</td>
</tr>
</tbody>
</table>

**TOTAL:** 3,828 $155,294,304.00

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 the new law; (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 Patients' Bill of Rights-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 plans/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 the Patients' Bill of Rights Act, HHS and DOL would have to promulgate 59 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 plans/issuers for compliance with the provisions in the Act governing the
professional/provider - health plan/issuer relationship; (2) all health plan/issuer policies, procedures and standards for the credentialing of health professionals and providers; (3) all marketing and informational materials of health plans/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 the Patients' Bill of Rights Act 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 the new law. 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.\(^1\) Approximately 70.2% of these contacts would be covered by the Patients' Bill of Rights Act, because 70.2% of the U.S. population has private health insurance.\(^2\) Therefore, a conservative estimate of the annual number of provider-patient contacts that would be subject to regulation under the new law 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 Patients' Bill of Rights Act 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

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\(^1\) *Statistical Abstract of the U.S.: 1995*, Table No. 178 at 122.

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 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., 0.0005%) of the annual physician/dentist - patient contacts subject to regulation under the new law.)

- 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 the Patients' Bill of Rights Act.

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 the Patients' Bill of Rights Act, 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.