

MEDICARE REGULATORY, APPEALS, CONTRACTING, AND
EDUCATION REFORM ACT OF 2001

DECEMBER 4, 2001.—Ordered to be printed

Mr. TAUZIN, from the Committee on Energy and Commerce,
submitted the following

R E P O R T

[To accompany H.R. 3046]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 3046) to amend title XVIII of the Social Security Act to provide regulatory relief, appeals process reforms, contracting flexibility, and education improvements under the Medicare Program, and for other purposes, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

CONTENTS

| | Page |
|---|------|
| Amendment | 1 |
| Purpose and Summary | 33 |
| Background and Need for Legislation | 33 |
| Hearings | 35 |
| Committee Consideration | 36 |
| Committee Votes | 36 |
| Committee Oversight Findings | 36 |
| Statement of General Performance Goals and Objectives | 36 |
| New Budget Authority, Entitlement Authority, and Tax Expenditures | 36 |
| Committee Cost Estimate | 36 |
| Congressional Budget Office Estimate | 37 |
| Federal Mandates Statement | 44 |
| Advisory Committee Statement | 44 |
| Constitutional Authority Statement | 44 |
| Applicability to Legislative Branch | 44 |
| Section-by-Section Analysis of the Legislation | 45 |
| Changes in Existing Law Made by the Bill, as Reported | 70 |

AMENDMENT

The amendment is as follows:
Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE; AMENDMENTS TO SOCIAL SECURITY ACT; TABLE OF CONTENTS.

(a) **SHORT TITLE.**—This Act may be cited as the “Medicare Regulatory, Appeals, Contracting, and Education Reform Act of 2001”.

(b) **AMENDMENTS TO SOCIAL SECURITY ACT.**—Except as otherwise specifically provided, whenever in this Act an amendment is expressed in terms of an amendment to or repeal of a section or other provision, the reference shall be considered to be made to that section or other provision of the Social Security Act.

(c) **BIPA; SECRETARY.**—In this Act:

(1) **BIPA.**—The term “BIPA” means the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, as enacted into law by section 1(a)(6) of Public Law 106–554.

(2) **SECRETARY.**—The term “Secretary” means the Secretary of Health and Human Services.

(d) **TABLE OF CONTENTS.**—The table of contents of this Act is as follows:

Sec. 1. Short title; amendments to Social Security Act; table of contents.

Sec. 2. Findings.

Sec. 3. Construction.

TITLE I—REGULATORY REFORM

Sec. 101. Issuance of regulations.

Sec. 102. Compliance with changes in regulations and policies.

Sec. 103. Report on regulatory burdens.

Sec. 104. GAO report on the sustainable growth rate and regulatory costs.

Sec. 105. GAO report on requirement for submission of claims for categorically excluded dental services.

TITLE II—APPEALS PROCESS REFORM

Sec. 201. Transfer of responsibility for medicare appeals.

Sec. 202. Expedited access to judicial review.

Sec. 203. Expedited review of certain provider agreement determinations.

Sec. 204. Revisions to medicare appeals process.

Sec. 205. Hearing rights related to decisions by the Secretary to deny or not renew a medicare enrollment agreement.

Sec. 206. Appeals by providers when there is no other party available.

Sec. 207. Process for exceptions to national coverage determinations under special medical circumstances.

Sec. 208. Prior determination process for certain items and services.

Sec. 209. BIPA-related technical amendments and corrections.

TITLE III—CONTRACTING REFORM

Sec. 301. Increased flexibility in medicare administration.

Sec. 302. Requirements for information security.

TITLE IV—EDUCATION AND OUTREACH IMPROVEMENTS

Sec. 401. Provider education and technical assistance.

Sec. 402. Access to and prompt responses from medicare administrative contractors.

Sec. 403. Reliance on guidance.

Sec. 404. Facilitation of consistent information to providers.

Sec. 405. Policy development regarding evaluation and management (E & M) documentation guidelines.

Sec. 406. Beneficiary outreach demonstration program; report on 1-800 medicare number.

Sec. 407. Provider enrollment applications.

TITLE V—REVIEW, RECOVERY, AND ENFORCEMENT REFORM

Sec. 501. Prepayment review.

Sec. 502. Recovery of overpayments.

Sec. 503. Process for correction of minor errors and omissions on claims without pursuing appeals process.

Sec. 504. Authority to waive a program exclusion.

TITLE VI—EMTALA IMPROVEMENTS

Sec. 601. Payment for EMTALA-mandated screening and stabilization services.

Sec. 602. Emergency Medical Treatment and Active Labor Act (EMTALA) Task Force.

Sec. 603. Notification of providers when EMTALA investigation closed.

Sec. 604. Prior review by peer review organizations in EMTALA cases involving termination of participation.

TITLE VII—MISCELLANEOUS IMPROVEMENTS

Sec. 701. Methods for determining payment basis for new lab tests.

Sec. 702. One year delay in lock in procedures for Medicare+Choice plans.

SEC. 2. FINDINGS.

Congress finds the following:

(1) The overwhelming majority of providers of services, physicians, practitioners, facilities, and suppliers in the United States are law-abiding persons who provide important health care services to patients each day.

(2) The Secretary of Health and Human Services should work to streamline paperwork requirements under the medicare program and communicate clearer instructions to providers of services, physicians, practitioners, facilities, and suppliers so that they may spend more time caring for patients.

SEC. 3. CONSTRUCTION.

(a) **NO EFFECT ON LEGAL AUTHORITY.**—Nothing in this Act shall be construed to compromise or affect existing legal authority for addressing fraud or abuse, whether

it be criminal prosecution, civil enforcement, or administrative remedies, including under sections 3729 through 3733 of title 31, United States Code (known as the False Claims Act).

(b) NO EFFECT ON MEDICARE WASTE, FRAUD, AND ABUSE EFFORTS.—Nothing in this Act shall be construed to prevent or impede the Department of Health and Human Services in any way from its ongoing efforts to eliminate waste, fraud, and abuse in the medicare program.

(c) CLARIFICATION RELATED TO MEDICARE TRUST FUNDS.—The consolidation of medicare administrative contracting set forth in this Act does not constitute (or reflect any position on the issue of) consolidation of the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund.

TITLE I—REGULATORY REFORM

SEC. 101. ISSUANCE OF REGULATIONS.

(a) CONSOLIDATION OF PROMULGATION TO ONCE A MONTH.—

(1) IN GENERAL.—Section 1871 (42 U.S.C. 1395hh) is amended by adding at the end the following new subsection:

“(d)(1) Subject to paragraph (2), the Secretary shall issue final (including interim final) regulations to carry out this title only on one business day of every month.

“(2) The Secretary may issue a final regulation described in paragraph (1) on any other day than the day described in paragraph (1) if the Secretary—

“(A) finds that issuance of such regulation on another day is necessary to comply with requirements under law; or

“(B) finds that with respect to that regulation the limitation of issuance on the date described in paragraph (1) is contrary to the public interest.

If the Secretary makes a finding under this paragraph, the Secretary shall include such finding, and brief statement of the reasons for such finding, in the issuance of such regulation.”

(2) REPORT ON PUBLICATION OF REGULATIONS ON A QUARTERLY BASIS.—Not later than 3 years after the date of the enactment of this Act, the Comptroller General of the United States shall submit to Congress a report on the feasibility of requiring that regulations described in section 1871(d) of the Social Security Act be promulgated on a quarterly basis rather than on a monthly basis.

(3) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to regulations promulgated on or after the date that is 30 days after the date of the enactment of this Act.

(b) REGULAR TIMELINE FOR PUBLICATION OF FINAL REGULATIONS.—

(1) IN GENERAL.—Section 1871(a) (42 U.S.C. 1395hh(a)) is amended by adding at the end the following paragraph:

“(3)(A) The Secretary, in consultation with the Director of the Office of Management and Budget, shall establish a regular timeline for the publication of final regulations based on the previous publication of a proposed regulation or an interim final regulation.

“(B) With respect to publication of final regulations based on the previous publication of a proposed regulation, such timeline may vary among different regulations based on differences in the complexity of the regulation, the number and scope of comments received, and other relevant factors.

“(C)(i) With respect to the publication of final regulations based on the previous publication of an interim final regulation—

“(I) subject to clause (ii), the Secretary shall publish the final regulation within the 12-month period that begins on the date of publication of the interim final regulation;

“(II) if a final regulation is not published by the deadline established under this subparagraph, the interim final regulation shall not continue in effect unless the Secretary publishes a notice described in clause (ii) by such deadline; and

“(III) the final regulation shall include responses to comments submitted in response to the interim final regulation.

“(ii) If the Secretary determines before the deadline otherwise established in this subparagraph that there is good cause, specified in a notice published before such deadline, for delaying the deadline otherwise applicable under this subparagraph, the deadline otherwise established under this subparagraph shall be extended for such period as the Secretary specifies in such notice.”

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on the date of the enactment of this Act. The Secretary shall provide for an appropriate transition to take into account the backlog of previously published interim final regulations.

(c) LIMITATIONS ON NEW MATTER IN FINAL REGULATIONS.—

(1) **IN GENERAL.**—Section 1871(a) (42 U.S.C. 1395hh(a)), as amended by subsection (b), is further amended by adding at the end the following new paragraph:

“(4) Insofar as a final regulation (other than an interim final regulation) includes a provision that is not a logical outgrowth of the relevant notice of proposed rulemaking relating to such regulation, that provision shall be treated as a proposed regulation and shall not take effect until there is the further opportunity for public comment and a publication of the provision again as a final regulation.”

(2) **EFFECTIVE DATE.**—The amendment made by paragraph (1) shall apply to final regulations published on or after the date of the enactment of this Act.

SEC. 102. COMPLIANCE WITH CHANGES IN REGULATIONS AND POLICIES.**(a) NO RETROACTIVE APPLICATION OF SUBSTANTIVE CHANGES.—**

(1) **IN GENERAL.**—Section 1871 (42 U.S.C. 1395hh), as amended by section 101(a), is amended by adding at the end the following new subsection:

“(e)(1)(A) A substantive change in regulations, manual instructions, interpretative rules, statements of policy, or guidelines of general applicability under this title shall not be applied (by extrapolation or otherwise) retroactively to items and services furnished before the effective date of the change, unless the Secretary determines that—

“(i) such retroactive application is necessary to comply with statutory requirements; or

“(ii) failure to apply the change retroactively would be contrary to the public interest.”

(2) **EFFECTIVE DATE.**—The amendment made by paragraph (1) shall apply to substantive changes issued on or after the date of the enactment of this Act.

(b) TIMELINE FOR COMPLIANCE WITH SUBSTANTIVE CHANGES AFTER NOTICE.—

(1) **IN GENERAL.**—Section 1871(e)(1), as added by subsection (a), is further amended by adding at the end the following:

“(B) A compliance action may be made against a provider of services, physician, practitioner, facility, or supplier with respect to noncompliance with a substantive change referred to in subparagraph (A) only for items and services furnished on or after the effective date of the change.

“(C)(i) Except as provided in clause (ii), a substantive change referred to in subparagraph (A) may not take effect before the end of the 30-day period that begins on the date that the Secretary has issued or published, as the case may be, the substantive change.

“(ii) The Secretary may provide for such a substantive change to take effect on a date that precedes the end of the 30-day period under clause (i) if the Secretary finds that waiver of such 30-day period is necessary to comply with statutory requirements or that the application of such 30-day period is contrary to the public interest. If the Secretary provides for an earlier effective date pursuant to this clause, the Secretary shall include in the issuance or publication of the substantive change a finding described in the first sentence, and a brief statement of the reasons for such finding.”

(2) **EFFECTIVE DATE.**—The amendment made by paragraph (1) shall apply to compliance actions undertaken on or after the date of the enactment of this Act.

SEC. 103. REPORT ON REGULATORY BURDENS.

Section 1871 (42 U.S.C. 1395hh), as amended by sections 101(a) and 102, is amended by adding at the end the following new subsection:

“(f)(1) Not later than 2 years after the date of the enactment of this subsection, and every 2 years thereafter, the Secretary shall submit to Congress a report with respect to the administration of this title and areas of inconsistency or conflict among the various provisions under law and regulation.

“(2) In preparing a report under paragraph (1), the Secretary shall collect—

“(A) information from beneficiaries, providers of services, physicians, practitioners, facilities, and suppliers, and from the individual under section 404 of the Medicare Regulatory, Appeals, Contracting, and Education Reform Act of 2001 with respect to such areas of inconsistency and conflict; and

“(B) information from medicare contractors that tracks the nature of written and telephone inquiries.

“(3) A report under paragraph (1) shall include a description of efforts by the Secretary to reduce such inconsistency or conflicts, and recommendations for legislation or administrative action that the Secretary determines appropriate to further reduce such inconsistency or conflicts.”

SEC. 104. GAO REPORT ON THE SUSTAINABLE GROWTH RATE AND REGULATORY COSTS.

Not later than 18 months after the date of the enactment of this Act, the Comptroller General of the United States shall submit to Congress a report on the accuracy of the sustainable growth rate (under section 1848(f) of the Social Security Act, 42 U.S.C. 1395w-4(f) for 2002 and succeeding years in accounting for regulatory costs imposed on physicians.

SEC. 105. GAO REPORT ON REQUIREMENT FOR SUBMISSION OF CLAIMS FOR CATEGORICALLY EXCLUDED DENTAL SERVICES.

Not later than 18 months after the date of the enactment of this Act, the Comptroller General of the United States shall submit to Congress a report on the extent to which—

- (1) group health plans or other third party payors require that claims for medicare categorically excluded dental services be denied by under the medicare program before the plan or payor will make payment for such claims; and
- (2) medicare beneficiaries request dentists to submit claims for such categorically excluded dental services.

TITLE II—APPEALS PROCESS REFORM**SEC. 201. TRANSFER OF RESPONSIBILITY FOR MEDICARE APPEALS.****(a) TRANSITION PLAN.—**

(1) **IN GENERAL.**—Not later than October 1, 2002, the Commissioner of Social Security and the Secretary shall develop and transmit to Congress and the Comptroller General of the United States a plan under which the functions of administrative law judges responsible for hearing cases under title XVIII of the Social Security Act (and related provisions in title XI of such Act) are transferred from the responsibility of the Commissioner and the Social Security Administration to the Secretary and the Department of Health and Human Services.

(2) **CONTENTS.**—The plan shall include information on the following:

(A) **WORKLOAD.**—The number of such administrative law judges and support staff required now and in the future to hear and decide such cases in a timely manner, taking into account the current and anticipated claims volume, appeals, number of beneficiaries, and statutory changes.

(B) **COST PROJECTIONS.**—Funding levels required for fiscal year 2004 and subsequent fiscal years under this subsection to hear such cases in a timely manner.

(C) **TRANSITION TIMETABLE.**—A timetable for the transition.

(D) **REGULATIONS.**—The establishment of specific regulations to govern the appeals process.

(E) **CASE TRACKING.**—The development of a unified case tracking system that will facilitate the maintenance and transfer of case specific data across both the fee-for-service and managed care components of the medicare program.

(F) **FEASIBILITY OF PRECEDENTIAL AUTHORITY.**—The feasibility of developing a process to give decisions of the Departmental Appeals Board in the Department of Health and Human Services addressing broad legal issues binding, precedential authority.

(G) **ACCESS TO ADMINISTRATIVE LAW JUDGES.**—The feasibility of filing appeals with administrative law judges electronically, and the feasibility of conducting hearings using tele- or video-conference technologies.

(3) **ADDITIONAL INFORMATION.**—The plan may also include recommendations for further Congressional action, including modifications to the requirements and deadlines established under section 1869 of the Social Security Act (as amended by sections 521 and 522 of BIPA, 114 Stat. 2763A-534).

(4) **GAO EVALUATION.**—The Comptroller General of the United States shall evaluate the plan and, not later than April 1, 2003, shall submit to Congress a report on such evaluation.

(b) TRANSFER OF ADJUDICATION AUTHORITY.—

(1) **IN GENERAL.**—Not earlier than July 1, 2003, and not later than October 1, 2003, the Commissioner of Social Security and the Secretary shall implement the transition plan under subsection (a) and transfer the administrative law judge functions described in such subsection from the Social Security Administration to the Secretary.

(2) **ASSURING INDEPENDENCE OF JUDGES.**—The Secretary shall assure the independence of judges performing the administrative law judge functions

transferred under paragraph (1) from the Centers for Medicare & Medicaid Services and its contractors.

(3) GEOGRAPHIC DISTRIBUTION.—The Secretary shall provide for an appropriate geographic distribution of judges performing the administrative law judge functions transferred under paragraph (1) throughout the United States to ensure timely access to such judges.

(4) HIRING AUTHORITY.—Subject to the amounts provided in advance in appropriations Act, the Secretary shall have authority to hire administrative law judges to hear such cases, giving priority to those judges with prior experience in handling medicare appeals and in a manner consistent with paragraph (3), and to hire support staff for such judges.

(5) FINANCING.—Amounts payable under law to the Commissioner for judges performing the administrative law judge functions transferred under paragraph (1) from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund shall become payable to the Secretary for the functions so transferred.

(6) SHARED RESOURCES.—The Secretary shall enter into such arrangements with the Commissioner as may be appropriate with respect to transferred functions of administrative law judges to share office space, support staff, and other resources, with appropriate reimbursement from the Trust Funds described in paragraph (5).

(c) INCREASED FINANCIAL SUPPORT.—In addition to any amounts otherwise appropriated, to ensure timely action on appeals before administrative law judges and the Departmental Appeals Board consistent with section 1869 of the Social Security Act (as amended by section 521 of BIPA, 114 Stat. 2763A–534), there are authorized to be appropriated (in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) to the Secretary such sums as are necessary for fiscal year 2003 and each subsequent fiscal year to—

(1) increase the number of administrative law judges (and their staffs) under subsection (b)(4);

(2) improve education and training opportunities for administrative law judges (and their staffs); and

(3) increase the staff of the Departmental Appeals Board.

(d) CONFIRMING AMENDMENT.—Section 1869(f)(2)(A)(i) (42 U.S.C. 1395ff(f)(2)(A)(i)), as added by section 522(a) of BIPA 114 Stat. 2763A–543, is amended by striking “of the Social Security Administration”.

SEC. 202. EXPEDITED ACCESS TO JUDICIAL REVIEW.

(a) IN GENERAL.—Section 1869(b) (42 U.S.C. 1395ff(b)), as amended by section 521 of BIPA, 114 Stat. 2763A–534, is amended—

(1) in paragraph (1)(A), by inserting “, subject to paragraph (2),” before “to judicial review of the Secretary’s final decision”; and

(2) by adding at the end the following new paragraph:

“(2) EXPEDITED ACCESS TO JUDICIAL REVIEW.—

“(A) IN GENERAL.—The Secretary shall establish a process under which a provider of services or supplier that furnishes an item or service or a beneficiary who has filed an appeal under paragraph (1) may obtain access to judicial review when a review panel (described in subparagraph (D)), on its own motion or at the request of the appellant, determines that the Departmental Appeals Board does not have the authority to decide the question of law or regulation relevant to the matters in controversy and that there is no material issue of fact in dispute. The appellant may make such request only once with respect to a question of law or regulation for a specific matter in dispute in a case of an appeal.

“(B) PROMPT DETERMINATIONS.—If, after or coincident with appropriately filing a request for an administrative hearing, the appellant requests a determination by the appropriate review panel that the Departmental Appeals Board does not have the authority to decide the question of law or regulations relevant to the matters in controversy and that there is no material issue of fact in dispute and if such request is accompanied by the documents and materials as the appropriate review panel shall require for purposes of making such determination, such review panel shall make a determination on the request in writing within 60 days after the date such review panel receives the request and such accompanying documents and materials. Such a determination by such review panel shall be considered a final decision and not subject to review by the Secretary.

“(C) ACCESS TO JUDICIAL REVIEW.—

“(i) IN GENERAL.—If the appropriate review panel—

“(I) determines that there are no material issues of fact in dispute and that the only issue is one of law or regulation that the Departmental Appeals Board does not have authority to decide; or
 “(II) fails to make such determination within the period provided under subparagraph (B);

then the appellant may bring a civil action as described in this subparagraph.

“(ii) DEADLINE FOR FILING.—Such action shall be filed, in the case described in—

“(I) clause (i)(I), within 60 days of the date of the determination described in such subparagraph; or

“(II) clause (i)(II), within 60 days of the end of the period provided under subparagraph (B) for the determination.

“(iii) VENUE.—Such action shall be brought in the district court of the United States for the judicial district in which the appellant is located (or, in the case of an action brought jointly by more than one applicant, the judicial district in which the greatest number of applicants are located) or in the district court for the District of Columbia.

“(iv) INTEREST ON ANY AMOUNTS IN CONTROVERSY.—Where a provider of services or supplier seeks judicial review pursuant to this paragraph, the amount in controversy (if any) shall be subject to annual interest beginning on the first day of the first month beginning after the 60-day period as determined pursuant to clause (ii) and equal to the rate of interest on obligations issued for purchase by the Federal Supplementary Medical Insurance Trust Fund for the month in which the civil action authorized under this paragraph is commenced, to be awarded by the reviewing court in favor of the prevailing party. No interest awarded pursuant to the preceding sentence shall be deemed income or cost for the purposes of determining reimbursement due providers of services and suppliers under this Act.

“(D) REVIEW PANEL DEFINED.—For purposes of this subsection, a ‘review panel’ is a panel of 3 members from the Departmental Appeals Board, selected for the purpose of making determinations under this paragraph.”

(b) APPLICATION TO PROVIDER AGREEMENT DETERMINATIONS.—Section 1866(h)(1) (42 U.S.C. 1395cc(h)(1)) is amended—

(1) by inserting “(A)” after “(h)(1)”; and

(2) by adding at the end the following new subparagraph:

“(B) An institution or agency described in subparagraph (A) that has filed for a hearing under subparagraph (A) shall have expedited access to judicial review under this subparagraph in the same manner as providers of services, suppliers, and beneficiaries may obtain expedited access to judicial review under the process established under section 1869(b)(2). Nothing in this subparagraph shall be construed to affect the application of any remedy imposed under section 1819 during the pendency of an appeal under this subparagraph.”

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to appeals filed on or after October 1, 2003.

SEC. 203. EXPEDITED REVIEW OF CERTAIN PROVIDER AGREEMENT DETERMINATIONS.

(a) TERMINATION AND IMMEDIATE SANCTIONS.—The Secretary shall develop and implement a process to expedite proceedings under sections 1866(h) of the Social Security Act (42 U.S.C. 1395cc(h)) in which the sanction of termination of participation or a sanction described in clause (i) or (iii) of section 1819(h)(2)(B) of such Act (42 U.S.C. 1395i–3(h)(2)(B)) has been imposed. Under such process priority shall be provided in cases of termination.

(b) INCREASED FINANCIAL SUPPORT.—In addition to any amounts otherwise appropriated, to reduce by 50 percent the average time for administrative determinations on appeals under section 1866(h) of the Social Security Act (42 U.S.C. 1395cc(h)), there are authorized to be appropriated (in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) to the Secretary such additional sums for fiscal year 2003 and each subsequent fiscal year as may be necessary to increase the number of administrative law judges (and their staffs) at the Departmental Appeals Board of the Department of Health and Human Services and to educate such judges and staff on long-term care issues.

SEC. 204. REVISIONS TO MEDICARE APPEALS PROCESS.

(a) TIMEFRAMES FOR THE COMPLETION OF THE RECORD.—Section 1869(b) (42 U.S.C. 1395ff(b)), as amended by section 521 of BIPA, 114 Stat. 2763A–534, and as amended in section 202(a), is further amended by adding at the end the following new paragraph:

“(3) TIMELY COMPLETION OF THE RECORD.—

“(A) DEADLINE.—Subject to subparagraph (B), the deadline to complete the record in a hearing before an administrative law judge or a review by the Departmental Appeals Board is 90 days after the date the request for the appeal is filed.

“(B) EXTENSIONS FOR GOOD CAUSE.—The person filing a request under subparagraph (A) may request an extension of such deadline for good cause. The administrative law judge, in the case of a hearing, and the Departmental Appeals Board in the case of a review, may extend such deadline based upon a finding of good cause to a date specified by such individual.

“(C) DELAY IN DECISION DEADLINES UNTIL COMPLETION OF RECORD.—Notwithstanding any other provision of this section, the deadlines otherwise established under subsection (d) for the making of determinations in hearings or review under this section shall begin on the date on which the record is complete.

“(D) COMPLETE DESCRIBED.—For purposes of this paragraph, a record is complete when the administrative law judge, in the case of a hearing, or the Departmental Appeals Board, in the case of a review, has received—

“(i) written or testimonial evidence, or both, submitted by the person filing the request,

“(ii) written or oral argument, or both, is presented,

“(iii) the decision of, and the record for, the prior level of appeal,

“(iv) such other evidence as such judge or Board, as the case may be, determines is required to make a determination on the request.”.

(b) USE OF PATIENTS’ MEDICAL RECORDS.—Section 1869(c)(3)(B)(i) (42 U.S.C. 1395ff(c)(3)(B)(i)) is amended by inserting “(including the medical records of the individual involved)” after “clinical experience”.

(c) NOTICE REQUIREMENTS FOR MEDICARE APPEALS.—

(1) INITIAL DETERMINATIONS AND REDETERMINATIONS.—Section 1869(a) (42 U.S.C. 1395ff(a)) is amended by adding at the end the following new paragraph:

“(4) REQUIREMENTS OF NOTICE OF DETERMINATIONS AND REDETERMINATIONS.—A written notice of a determination on an initial determination or on a redetermination, insofar as such determination or redetermination results in a denial of a claim for benefits, shall be provided in printed form and written in a manner calculated to be understood by the beneficiary and shall include—

“(A) the specific reasons for the determination, including, as appropriate—

“(i) upon request in the case of an initial determination, a summary of the clinical or scientific evidence used in making the determination; and

“(ii) in the case of a redetermination, such a summary;

“(B) the procedures for obtaining additional information concerning the determination or redetermination; and

“(C) notification of the right to seek a redetermination or otherwise appeal the determination and instructions on how to initiate such a redetermination or appeal under this section.”.

(2) RECONSIDERATIONS.—Section 1869(c)(3)(E) (42 U.S.C. 1395ff(c)(3)(E)) is amended—

(A) by inserting “be written in a manner calculated to be understood by the beneficiary, and shall include (to the extent appropriate)” after “in writing, ”; and

(B) by inserting “and a notification of the right to appeal such determination and instructions on how to initiate such appeal under this section” after “such decision, ”.

(3) APPEALS.—Section 1869(d) (42 U.S.C. 1395ff(d)) is amended—

(A) in the heading, by inserting “; NOTICE” after “SECRETARY”; and

(B) by adding at the end the following new paragraph:

“(4) NOTICE.—Notice of the decision of an administrative law judge shall be in writing in a manner calculated to be understood by the beneficiary and shall include—

“(A) the specific reasons for the determination (including, to the extent appropriate, a summary of the clinical or scientific evidence used in making the determination);

“(B) the procedures for obtaining additional information concerning the decision; and

“(C) notification of the right to appeal the decision and instructions on how to initiate such an appeal under this section.”.

- (4) PREPARATION OF RECORD FOR APPEAL.—Section 1869(c)(3)(J) (42 U.S.C. 1395ff(c)(3)(J)) by striking “such information as is required for an appeal” and inserting “the record for the appeal”.
- (d) QUALIFIED INDEPENDENT CONTRACTORS.—
- (1) ELIGIBILITY REQUIREMENTS OF QUALIFIED INDEPENDENT CONTRACTORS.—Section 1869(c) (42 U.S.C. 1395ff(c)) is amended—
- (A) in paragraph (2)—
- (i) by inserting “(except in the case of a utilization and quality control peer review organization, as defined in section 1152)” after “means an entity or organization that”; and
- (ii) by striking the period at the end and inserting the following: “and meets the following requirements:
- “(A) GENERAL REQUIREMENTS.—
- “(i) The entity or organization has (directly or through contracts or other arrangements) sufficient medical, legal, and other expertise (including knowledge of the program under this title) and sufficient staffing to carry out duties of a qualified independent contractor under this section on a timely basis.
- “(ii) The entity or organization has provided assurances that it will conduct activities consistent with the applicable requirements of this section, including that it will not conduct any activities in a case unless the independence requirements of subparagraph (B) are met with respect to the case.
- “(iii) The entity or organization meets such other requirements as the Secretary provides by regulation.
- “(B) INDEPENDENCE REQUIREMENTS.—
- “(i) IN GENERAL.—Subject to clause (ii), an entity or organization meets the independence requirements of this subparagraph with respect to any case if the entity—
- “(I) is not a related party (as defined in subsection (g)(5));
- “(II) does not have a material familial, financial, or professional relationship with such a party in relation to such case; and
- “(III) does not otherwise have a conflict of interest with such a party (as determined under regulations).
- “(ii) EXCEPTION FOR REASONABLE COMPENSATION.—Nothing in clause (i) shall be construed to prohibit receipt by a qualified independent contractor of compensation from the Secretary for the conduct of activities under this section if the compensation is provided consistent with clause (iii).
- “(iii) LIMITATIONS ON ENTITY COMPENSATION.—Compensation provided by the Secretary to a qualified independent contractor in connection with reviews under this section shall—
- “(I) not exceed a reasonable level; and
- “(II) not be contingent on any decision rendered by the contractor or by any reviewing professional.”; and
- (B) in paragraph (3)(A), by striking “, and shall have sufficient training and expertise in medical science and legal matters to make reconsiderations under this subsection”.
- (2) ELIGIBILITY REQUIREMENTS FOR REVIEWERS.—Section 1869 (42 U.S.C. 1395ff) is amended—
- (A) by amending subsection (c)(3)(D) to read as follows:
- “(D) QUALIFICATIONS FOR REVIEWERS.—The requirements of subsection (g) shall be met (relating to qualifications of reviewing professionals).”; and
- (B) by adding at the end the following new subsection:
- “(g) QUALIFICATIONS OF REVIEWERS.—
- “(1) IN GENERAL.—In reviewing determinations under this section, a qualified independent contractor shall assure that—
- “(A) each individual conducting a review shall meet the qualifications of paragraph (2);
- “(B) compensation provided by the contractor to each such reviewer is consistent with paragraph (3); and
- “(C) in the case of a review by a panel described in subsection (c)(3)(B) composed of physicians or other health care professionals (each in this subsection referred to as a ‘reviewing professional’), each reviewing professional meets the qualifications described in paragraph (4) and, if the request for review indicates that the item or service involved was furnished (or ordered to be furnished) by a physician, each reviewing professional shall be a physician.
- “(2) INDEPENDENCE.—

“(A) IN GENERAL.—Subject to subparagraph (B), each individual conducting a review in a case shall—

“(i) not be a related party (as defined in paragraph (5));

“(ii) not have a material familial, financial, or professional relationship with such a party in the case under review; and

“(iii) not otherwise have a conflict of interest with such a party (as determined under regulations).

“(B) EXCEPTION.—Nothing in subparagraph (A) shall be construed to—

“(i) prohibit an individual, solely on the basis of affiliation with a fiscal intermediary, carrier, or other contractor, from serving as a reviewing professional if—

“(I) a non-affiliated individual is not reasonably available;

“(II) the affiliated individual is not involved in the provision of items or services in the case under review;

“(III) the fact of such an affiliation is disclosed to the Secretary and the beneficiary (or authorized representative) and neither party objects; and

“(IV) the affiliated individual is not an employee of the intermediary, carrier, or contractor and does not provide services exclusively or primarily to or on behalf of such intermediary, carrier, or contractor;

“(ii) prohibit an individual who has staff privileges at the institution where the treatment involved takes place from serving as a reviewer merely on the basis of such affiliation if the affiliation is disclosed to the Secretary and the beneficiary (or authorized representative), and neither party objects; or

“(iii) prohibit receipt of compensation by a reviewing professional from a contractor if the compensation is provided consistent with paragraph (3).

“(3) LIMITATIONS ON REVIEWER COMPENSATION.—Compensation provided by a qualified independent contractor to a reviewer in connection with a review under this section shall—

“(A) not exceed a reasonable level; and

“(B) not be contingent on the decision rendered by the reviewer.

“(4) LICENSURE AND EXPERTISE.—Each reviewing professional shall be a physician (allopathic or osteopathic) or health care professional who—

“(A) is appropriately credentialed or licensed in 1 or more States to deliver health care services; and

“(B) typically treats the condition, makes the diagnosis, or provides the type of treatment under review.

“(5) RELATED PARTY DEFINED.—For purposes of this section, the term ‘related party’ means, with respect to a case under this title involving an individual beneficiary, any of the following:

“(A) The Secretary, the medicare administrative contractor involved, or any fiduciary, officer, director, or employee of the Department of Health and Human Services, or of such contractor.

“(B) The individual (or authorized representative).

“(C) The health care professional that provides the items or services involved in the case.

“(D) The institution at which the items or services (or treatment) involved in the case are provided.

“(E) The manufacturer of any drug or other item that is included in the items or services involved in the case.

“(F) Any other party determined under any regulations to have a substantial interest in the case involved.”

(e) IMPLEMENTATION OF CERTAIN BIPA REFORMS.—

(1) 1-YEAR DELAY IN EFFECTIVE DATES.—(A) Section 521(d) of BIPA (114 Stat. 2763A–543) is amended by striking “October 1, 2002” and inserting “October 1, 2003”.

(B) Section 522(d) of BIPA (114 Stat. 2763A–547) is amended by striking “October 1, 2001” and inserting “October 1, 2002”.

(2) USE OF PEER REVIEW ORGANIZATIONS TO CONDUCT EXPEDITED REVIEW DURING TRANSITION PERIOD.—

(A) IN GENERAL.—Section 1154(e) (42 U.S.C. 1320c–3(e)) is amended by adding at the end the following:

“(6)(A) In applying this subsection during the transition period (described in subparagraph (C)), any reference in this subsection—

“(i) to a hospital is deemed a reference to a provider of services;

“(ii) to inpatient hospital care or services is deemed a reference to services of such a provider of services;

“(iii) a notice under paragraph (1) is deemed to include—

“(I) a notice to discharge the individual from the provider of services; or
“(II) a notice of termination of services by a provider of services, but only in the case in which a physician certifies that failure to continue the provision of such services is likely to place the individual’s health at significant risk; and

“(iv) an inpatient is deemed a reference to a patient.

“(B) After the transition period, paragraphs (2) through (5) shall not apply.

“(C) For purposes of this paragraph and section 1869(b)(1)(F)(ii), the transition period, with respect to an individual who resides in an area served by a peer review organization—

“(i) begins on the date on which the last triennial contract with any peer review organization under this part becomes effective during 2002; and

“(ii) ends on the date that the triennial contract under this part with the organization that serves such area expires in 2006.”.

(B) CONFORMING AMENDMENT TO BIPA.—Subsection (c) of section 521 of BIPA is repealed.

(C) CONFORMING AMENDMENT TO SECTION 1869.—Section 1869(b)(1)(F) (42 U.S.C. 1395ff(b)(1)(F)), as amended by section 521 of BIPA, is amended by striking clause (ii) and inserting the following:

“(ii) NO APPLICATION DURING TRANSITION PERIOD.—Clause (i) shall not apply during the transition period described in section 1154(e)(6)(C).”.

(D) SECTION 1155 TRANSITION.—Section 1155 (42 U.S.C. 1320c–4) is amended by adding at the end the following: “In the case of a determination made under section 1154(e)(6)(A) during the period in which the provisions of subsection (b) of section 1869 (as added by section 521 of Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, as enacted into law by section 1(a)(6) of Public Law 106–554) are in effect, this section shall not apply but the individual shall be entitled to a hearing on the determination before an administrative law judge under such subsection (b) in the same manner as such section applies to a hearing under subsection (a) of such section 1869.”.

(f) EFFECTIVE DATE.—The amendments made by this section shall be effective as if included in the enactment of the respective provisions of subtitle C of title V of BIPA, 114 Stat. 2763A–534.

(g) TRANSITION.—In applying section 1869(g) of the Social Security Act (as added by subsection (d)(2)), any reference to a medicare administrative contractor shall be deemed to include a reference to a fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and a carrier under section 1842 of such Act (42 U.S.C. 1395u).

SEC. 205. HEARING RIGHTS RELATED TO DECISIONS BY THE SECRETARY TO DENY OR NOT RENEW A MEDICARE ENROLLMENT AGREEMENT.

(a) HEARING RIGHTS.—Section 1866 (42 U.S.C. 1395cc) is amended by adding at the end the following new subsection:

“(j) HEARING RIGHTS IN CASES OF DENIAL OR NON-RENEWAL.—A provider of services, physician, practitioner, facility, or supplier whose application to enroll (or, if applicable, to renew enrollment) under this title is denied may have a hearing and judicial review of such denial under the procedures that apply under subsection (h)(1)(A) to a provider of services that is dissatisfied with a determination by the Secretary.”.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to denials occurring on or after such date (not later than 1 year after the date of the enactment of this Act) as the Secretary specifies.

SEC. 206. APPEALS BY PROVIDERS WHEN THERE IS NO OTHER PARTY AVAILABLE.

(a) IN GENERAL.—Section 1870 (42 U.S.C. 1395gg) is amended by adding at the end the following new subsection:

“(h) Notwithstanding subsection (f) or any other provision of law, the Secretary shall permit a provider of services, physician, practitioner, facility, or supplier to appeal any determination of the Secretary under this title relating to services rendered under this title to an individual who subsequently dies, if there is no other party available to appeal such determination, so long as the estate of the individual, and the individual’s family and heirs, are not liable for paying for the item or service and are not liable for any increased coinsurance or deductible amounts resulting from any decision increasing the reimbursement amount for the provider of services, physician, practitioner, facility, or supplier.”.

(b) **EFFECTIVE DATE.**—The amendment made by subsection (a) shall take effect on the date of the enactment of this Act and shall apply to items and services furnished on or after such date.

SEC. 207. PROCESS FOR EXCEPTIONS TO NATIONAL COVERAGE DETERMINATIONS UNDER SPECIAL MEDICAL CIRCUMSTANCES

(a) **IN GENERAL.**—Section 1869(f) (42 U.S.C. 1395fff), as added by section 522 of BIPA, is amended—

(1) by redesignating paragraphs (6) through (8) as paragraphs (7) through (9); and

(2) by inserting after paragraph (5) the following new paragraph:

“(6) **PROCESS FOR EXCEPTIONS TO NATIONAL COVERAGE DETERMINATIONS UNDER SPECIAL MEDICAL CIRCUMSTANCES.**—

“(A) **ESTABLISHMENT OF PROCESS.**—The Secretary shall establish a process whereby an individual described in paragraph (5) may submit to the Secretary a request for a determination that a national coverage determination, which has the effect of denying coverage under this title for items and services for the treatment of a serious or life-threatening condition of the individual, should not apply to the individual due to the special medical circumstances of the individual that involve medical factors that were not considered during the national coverage determination decisionmaking procedure and make the application of the national coverage determination inappropriate for the individual’s particular case. Such request shall be accompanied by supporting documentation and may be made before the receipt of the items or services involved.

“(B) **USE OF PANEL.**—Under such process, the Secretary shall provide that—

“(i) the initial decision on the request is made by a panel described in subparagraph (C); or

“(ii) the individual is provided the opportunity to appeal the initial decision on the request to such a panel.

“(C) **PANEL.**—A panel described in this subparagraph is a panel of physicians or other appropriate health care professionals in which each member of the panel meets the requirements of paragraphs (2) and (4) of subsection (g) (relating to independence and licensure and expertise).

“(D) **APPEAL.**—A decision on a request under this paragraph shall be subject to further review (after any appeal described in subparagraph (B)(ii)) by the Departmental Appeals Board and to judicial review, in the same manner as provided under subsection (b) with respect to review of a final decision of the Secretary.

“(E) **EXPEDITION.**—The process under this paragraph shall provide for reasonable expedition for making decisions on requests when the need for expedition is certified by a physician.

“(F) **EFFECT OF DECISION.**—If a request under this paragraph is approved for an individual with respect to a treatment, the national coverage determination shall not be applied by any medicare administrative contractor with respect to the treatment for that individual.

“(G) **NOTICE.**—The Secretary shall provide, in an appropriate annual publication available to the public, a list of national coverage determinations and information on how to get more information with respect to such determinations, made in the previous year.”

(b) **EFFECTIVE DATE.**—The amendments made by subsection (a) shall apply as if included in the enactment of section 522 of BIPA.

SEC. 208. PRIOR DETERMINATION PROCESS FOR CERTAIN ITEMS AND SERVICES.

(a) **IN GENERAL.**—Section 1869 (42 U.S.C. 1395ff(b)), as amended by sections 521 and 522 of BIPA and section 204(d)(2)(B), is further amended by adding at the end the following new subsection:

“(h) **PRIOR DETERMINATION PROCESS FOR CERTAIN ITEMS AND SERVICES.**—

“(1) **ESTABLISHMENT OF PROCESS.**—

“(A) **IN GENERAL.**—With respect to a medicare administrative contractor that has a contract under section 1874A that provides for making payments under this title with respect to items and services, the Secretary shall establish a prior determination process that meets the requirements of this subsection and that shall be applied by such contractor in the case of eligible requesters.

“(B) **ELIGIBLE REQUESTER.**—For purposes of this subsection, the term ‘eligible requester’ means—

“(i) a physician, but only in the case of items and services that may be furnished (or ordered to be furnished) by the physician; and

“(ii) an individual entitled to benefits under this title, but only with respect to an item or service for which the individual receives an advance beneficiary notice from the provider or supplier of the item or service under section 1879 that payment may not be made (or may no longer be made) for the item or service under this title.

“(2) ESTABLISHING ELIGIBLE CATEGORIES.—The Secretary shall establish by regulation limits on the categories of items and services for which a prior determination of coverage may be requested under this subsection. In establishing such limits, the Secretary may consider the dollar amount involved with respect to the item or service, administrative costs and burdens, and other relevant factors.

“(3) REQUEST FOR PRIOR DETERMINATION.—

“(A) IN GENERAL.—Subject to paragraph (2), under the process established under this subsection any eligible requester may submit to the contractor a request for a determination, before the furnishing (or ordering the furnishing) of the item or service involved as to whether the item or service is covered under this title consistent with the applicable requirements of section 1862(a) (relating to medical necessity, etc.).

“(B) ACCOMPANYING DOCUMENTATION.—The request shall be accompanied by a description of the item or service, its billing code (as appropriate), supporting documentation relating to the medical necessity for the item or service, and any other appropriate documentation that the Secretary may require. In the case of a request submitted by an eligible requester that is described in paragraph (1)(B)(ii), the request shall also be accompanied by a copy of the advance beneficiary notice involved.

“(4) RESPONSE TO REQUEST.—

“(A) IN GENERAL.—Under such process, the contractor shall provide the eligible requester with written notice of a determination as to whether—

“(i) the item or service is so covered;

“(ii) the item or service is not so covered; or

“(iii) the contractor lacks sufficient information to make a coverage determination.

In the case of a request in which an eligible requester is not the beneficiary described in paragraph (1)(B)(i), the process shall provide that the beneficiary involved shall be informed of any determination described in clause (ii) (relating to a determination of non-coverage).

“(B) DEADLINE TO RESPOND.—Such notice shall be provided within the same time period as the time period applicable to the contractor providing notice of initial determinations on a claim for benefits under subsection (a)(2)(A).

“(5) EFFECT OF DETERMINATIONS.—

“(A) BINDING NATURE OF POSITIVE DETERMINATION.—If the contractor makes the determination described in paragraph (4)(A)(i), such determination shall be binding on the contractor in the absence of fraud or evidence of misrepresentation of facts presented to the contractor.

“(B) RIGHT TO REDETERMINATION IN CASE OF A DENIAL.—

“(i) IN GENERAL.—If the contractor makes the determination described in paragraph (4)(A)(ii)—

“(I) the eligible requester has the right to a redetermination by the contractor on the determination that the item or service is not so covered; and

“(II) the contractor shall include in notice under paragraph (4)(A) a brief explanation of the basis for the determination and the right to such a redetermination.

“(ii) DEADLINE FOR REDETERMINATIONS.—The contractor shall complete and provide notice of such redetermination within the same time period as the time period applicable to the contractor providing notice of redeterminations relating to a claim for benefits under subsection (a)(3)(C)(ii).

“(C) DESCRIPTION OF ADDITIONAL INFORMATION REQUIRED.—If the contractor makes the determination described in paragraph (4)(A)(iii), the contractor shall include in the notice under paragraph (4)(A) a description of the additional information required to make the coverage determination.

“(6) LIMITATION ON FURTHER REVIEW.—

“(A) IN GENERAL.—Contractor determinations described in paragraph (4)(A)(ii) or (4)(A)(iii) (and redeterminations made under paragraph (5)(B)), relating to pre-service claims are not subject to further administrative appeal or judicial review under this section or otherwise.

“(B) CONSTRUCTION.—Nothing in this subsection shall be construed as affecting the right of an individual, after receiving items or services for which the contractor has made a determination described in paragraph (4)(A)(ii), from submitting a claim for such item or service or from obtaining administrative or judicial review respecting such claim under the other applicable provisions of this section.”.

(b) EFFECTIVE DATE; TRANSITION.—

(1) EFFECTIVE DATE.—The Secretary shall establish the prior determination process under the amendment made by subsection (a) in such a manner as to provide for the acceptance of requests for determinations under such process filed not later than 18 months after the date of the enactment of this Act.

(2) TRANSITION.—During the period in which the amendment made by subsection (a) has become effective but contracts are not provided under section 1874A of the Social Security Act with medicare administrative contractors, any reference in section 1869(g) of such Act (as added by such amendment) to such a contractor is deemed a reference to a fiscal intermediary or carrier with an agreement under section 1816, or contract under section 1842, respectively, of such Act.

(c) PROVISIONS RELATING TO ADVANCE BENEFICIARY NOTICES.—

(1) DATA COLLECTION.—The Secretary shall establish a process for the collection of information on the instances in which an advance beneficiary notice (as defined in paragraph (4)) has been provided and on instances in which a beneficiary indicates on such a notice that the beneficiary does not intend to seek to have the item or service that is the subject of the notice furnished.

(2) OUTREACH AND EDUCATION.—The Secretary shall establish a program of outreach and education for beneficiaries and providers of services and other persons on the appropriate use of advance beneficiary notices and coverage and coverage policies under the medicare program.

(3) GAO REPORT.—Not later than 18 months after the date on which section 1869(g) of the Social Security Act (as added by subsection (a)) takes effect, the Comptroller General of the United States shall submit to Congress a report on the use of advance beneficiary notices under title XVIII of such Act. Such report shall include information concerning the providers of services and other persons that have provided such notices and the response of beneficiaries to such notices, including the use of the prior determination process under such section 1869(g) and their receipt of services.

(4) ADVANCE BENEFICIARY NOTICE DEFINED.—In this subsection, the term “advance beneficiary notice” means a written notice provided under section 1879 of the Social Security Act (42 U.S.C. 1395pp) to an individual entitled to benefits under part A or B of title XVIII of such Act before items or services are furnished under such part in cases where a provider of services or other person that would furnish the item or service believes that payment will not be made for some or all of such items or services under such title on the basis that they are not reasonable and necessary consistent with the applicable requirements of section 1862(a) (relating to medical necessity, etc.) of such title.

SEC. 209. BIPA-RELATED TECHNICAL AMENDMENTS AND CORRECTIONS.

(a) TECHNICAL AMENDMENTS RELATING TO ADVISORY COMMITTEE UNDER BIPA SECTION 522.—(1) Subsection (i) of section 1114 (42 U.S.C. 1314)—

(A) is transferred to section 1862 and added at the end of such section; and

(B) is redesignated as subsection (j).

(2) Section 1862 (42 U.S.C. 1395y) is amended—

(A) in the last sentence of subsection (a), by striking “section 1114(f)” and inserting “section 222 of the Public Health Service Act”; and

(B) in subsection (j), as so transferred and redesignated—

(i) by striking “subsection (f)” and inserting “section 222 of the Public Health Service Act”;

(ii) by striking “section 1862(a)(1)” and inserting “subsection (a)(1)”.

(b) TERMINOLOGY CORRECTIONS.—(1) Section 1869(c)(3)(I)(ii) (42 U.S.C. 1395ff(c)(3)(I)(ii)), as amended by section 521 of BIPA, is amended—

(A) in subclause (III), by striking “policy” and inserting “determination”; and

(B) in subclause (IV), by striking “medical review policies” and inserting “coverage determinations”.

(2) Section 1852(a)(2)(C) (42 U.S.C. 1395w–22(a)(2)(C)) is amended by striking “policy” and “POLICY” and inserting “determination” each place it appears and “DETERMINATION”, respectively.

(c) REFERENCE CORRECTIONS.—Section 1869(f)(4) (42 U.S.C. 1395ff(f)(4)), as added by section 522 of BIPA, is amended—

- (1) in subparagraph (A)(iv), by striking “subclause (I), (II), or (III)” and inserting “clause (i), (ii), or (iii)”;
- (2) in subparagraph (B), by striking “clause (i)(IV)” and “clause (i)(III)” and inserting “subparagraph (A)(iv)” and “subparagraph (A)(iii)”, respectively; and
- (3) in subparagraph (C), by striking “clause (i)”, “subclause (IV)” and “subparagraph (A)” and inserting “subparagraph (A)”, “clause (iv)” and “paragraph (1)(A)”, respectively each place it appears.
- (d) EFFECTIVE DATE.—The amendments made by this section shall be effective as if included in the enactment of BIPA.

TITLE III—CONTRACTING REFORM

SEC. 301. INCREASED FLEXIBILITY IN MEDICARE ADMINISTRATION.

(a) CONSOLIDATION AND FLEXIBILITY IN MEDICARE ADMINISTRATION.—

- (1) IN GENERAL.—Title XVIII is amended by inserting after section 1874 the following new section:

“CONTRACTS WITH MEDICARE ADMINISTRATIVE CONTRACTORS

“SEC. 1874A. (a) AUTHORITY.—

“(1) AUTHORITY TO ENTER INTO CONTRACTS.—The Secretary may enter into contracts with any eligible entity to serve as a medicare administrative contractor with respect to the performance of any or all of the functions described in paragraph (4) or parts of those functions (or, to the extent provided in a contract, to secure performance thereof by other entities).

“(2) ELIGIBILITY OF ENTITIES.—An entity is eligible to enter into a contract with respect to the performance of a particular function or activity described in paragraph (4) only if—

- “(A) the entity has demonstrated capability to carry out such function;
- “(B) the entity complies with such conflict of interest standards as are generally applicable to Federal acquisition and procurement;
- “(C) the entity has sufficient assets to financially support the performance of such function; and
- “(D) the entity meets such other requirements as the Secretary may impose.

“(3) MEDICARE ADMINISTRATIVE CONTRACTOR DEFINED.—For purposes of this title and title XI—

“(A) IN GENERAL.—The term ‘medicare administrative contractor’ means an agency, organization, or other person with a contract under this section.

“(B) APPROPRIATE MEDICARE ADMINISTRATIVE CONTRACTOR.—With respect to the performance of a particular function or activity in relation to an individual entitled to benefits under part A or enrolled under part B, or both, a specific provider of services, physician, practitioner, facility, or supplier (or class of such providers of services, physicians, practitioners, facilities, or suppliers), the ‘appropriate’ medicare administrative contractor is the medicare administrative contractor that has a contract under this section with respect to the performance of that function or activity in relation to that individual, provider of services, physician, practitioner, facility, or supplier or class of provider of services, physician, practitioner, facility, or supplier.

“(4) FUNCTIONS DESCRIBED.—The functions referred to in paragraphs (1) and (2) are payment functions, provider services functions, and beneficiary services functions as follows:

“(A) DETERMINATION OF PAYMENT AMOUNTS.—Determining (subject to the provisions of section 1878 and to such review by the Secretary as may be provided for by the contracts) the amount of the payments required pursuant to this title to be made to providers of services, physicians, practitioners, facilities, suppliers, and individuals.

“(B) MAKING PAYMENTS.—Making payments described in subparagraph (A) (including receipt, disbursement, and accounting for funds in making such payments).

“(C) BENEFICIARY EDUCATION AND ASSISTANCE.—Serving as a center for, and communicating to individuals entitled to benefits under part A or enrolled under part B, or both, with respect to education and outreach for those individuals, and assistance with specific issues, concerns or problems of those individuals.

“(D) PROVIDER CONSULTATIVE SERVICES.—Providing consultative services to institutions, agencies, and other persons to enable them to establish and maintain fiscal records necessary for purposes of this title and otherwise to

qualify as providers of services, physicians, practitioners, facilities, or suppliers.

“(E) COMMUNICATION WITH PROVIDERS.—Serving as a center for, and communicating to providers of services, physicians, practitioners, facilities, and suppliers, any information or instructions furnished to the medicare administrative contractor by the Secretary, and serving as a channel of communication from such providers, physicians, practitioners, facilities, and suppliers to the Secretary.

“(F) PROVIDER EDUCATION AND TECHNICAL ASSISTANCE.—Performing the functions described in subsections (e) and (f), relating to education, training, and technical assistance to providers of services, physicians, practitioners, facilities, and suppliers.

“(G) ADDITIONAL FUNCTIONS.—Performing such other functions as are necessary to carry out the purposes of this title.

“(5) RELATIONSHIP TO MIP CONTRACTS.—

“(A) NONDUPLICATION OF DUTIES.—In entering into contracts under this section, the Secretary shall assure that functions of medicare administrative contractors in carrying out activities under parts A and B do not duplicate functions carried out under the Medicare Integrity Program under section 1893. The previous sentence shall not apply with respect to the activity described in section 1893(b)(5) (relating to prior authorization of certain items of durable medical equipment under section 1834(a)(15)).

“(B) CONSTRUCTION.—An entity shall not be treated as a medicare administrative contractor merely by reason of having entered into a contract with the Secretary under section 1893.

“(6) APPLICATION OF FEDERAL ACQUISITION REGULATION.—Except to the extent inconsistent with a specific requirement of this title, the Federal Acquisition Regulation applies to contracts under this title.

“(b) CONTRACTING REQUIREMENTS.—

“(1) USE OF COMPETITIVE PROCEDURES.—

“(A) IN GENERAL.—Except as provided in laws with general applicability to Federal acquisition and procurement or in subparagraph (B), the Secretary shall use competitive procedures when entering into contracts with medicare administrative contractors under this section.

“(B) RENEWAL OF CONTRACTS.—The Secretary may renew a contract with a medicare administrative contractor under this section from term to term without regard to section 5 of title 41, United States Code, or any other provision of law requiring competition, if the medicare administrative contractor has met or exceeded the performance requirements applicable with respect to the contract and contractor, except that the Secretary shall provide for the application of competitive procedures under such a contract not less frequently than once every five years.

“(C) TRANSFER OF FUNCTIONS.—The Secretary may transfer functions among medicare administrative contractors without regard to any provision of law requiring competition. The Secretary shall ensure that performance quality is considered in such transfers. The Secretary shall provide notice (whether in the Federal Register or otherwise) of any such transfer (including a description of the functions so transferred and contact information for the contractors involved) to providers of services, physicians, practitioners, facilities, and suppliers affected by the transfer.

“(D) INCENTIVES FOR QUALITY.—The Secretary shall provide incentives for medicare administrative contractors to provide quality service and to promote efficiency.

“(2) COMPLIANCE WITH REQUIREMENTS.—No contract under this section shall be entered into with any medicare administrative contractor unless the Secretary finds that such medicare administrative contractor will perform its obligations under the contract efficiently and effectively and will meet such requirements as to financial responsibility, legal authority, and other matters as the Secretary finds pertinent.

“(3) PERFORMANCE REQUIREMENTS.—

“(A) DEVELOPMENT OF SPECIFIC PERFORMANCE REQUIREMENTS.—The Secretary shall develop contract performance requirements to carry out the specific requirements applicable under this title to a function described in subsection (a)(4) and shall develop standards for measuring the extent to which a contractor has met such requirements. The Secretary shall publish in the Federal Register such performance requirements and measurement standards.

“(B) CONSIDERATIONS.—The Secretary may include as one of the standards satisfaction level as measured by provider and beneficiary surveys.

“(C) INCLUSION IN CONTRACTS.—All contractor performance requirements shall be set forth in the contract between the Secretary and the appropriate medicare administrative contractor. Such performance requirements—

“(i) shall reflect the performance requirements published under subparagraph (A), but may include additional performance requirements;

“(ii) shall be used for evaluating contractor performance under the contract; and

“(iii) shall be consistent with the written statement of work provided under the contract.

“(4) INFORMATION REQUIREMENTS.—The Secretary shall not enter into a contract with a medicare administrative contractor under this section unless the contractor agrees—

“(A) to furnish to the Secretary such timely information and reports as the Secretary may find necessary in performing his functions under this title; and

“(B) to maintain such records and afford such access thereto as the Secretary finds necessary to assure the correctness and verification of the information and reports under subparagraph (A) and otherwise to carry out the purposes of this title.

“(5) SURETY BOND.—A contract with a medicare administrative contractor under this section may require the medicare administrative contractor, and any of its officers or employees certifying payments or disbursing funds pursuant to the contract, or otherwise participating in carrying out the contract, to give surety bond to the United States in such amount as the Secretary may deem appropriate.

“(c) TERMS AND CONDITIONS.—

“(1) IN GENERAL.—A contract with any medicare administrative contractor under this section may contain such terms and conditions as the Secretary finds necessary or appropriate and may provide for advances of funds to the medicare administrative contractor for the making of payments by it under subsection (a)(4)(B).

“(2) PROHIBITION ON MANDATES FOR CERTAIN DATA COLLECTION.—The Secretary may not require, as a condition of entering into, or renewing, a contract under this section, that the medicare administrative contractor match data obtained other than in its activities under this title with data used in the administration of this title for purposes of identifying situations in which the provisions of section 1862(b) may apply.

“(d) LIMITATION ON LIABILITY OF MEDICARE ADMINISTRATIVE CONTRACTORS AND CERTAIN OFFICERS.—

“(1) CERTIFYING OFFICER.—No individual designated pursuant to a contract under this section as a certifying officer shall, in the absence of gross negligence or intent to defraud the United States, be liable with respect to any payments certified by the individual under this section.

“(2) DISBURSING OFFICER.—No disbursing officer shall, in the absence of gross negligence or intent to defraud the United States, be liable with respect to any payment by such officer under this section if it was based upon an authorization (which meets the applicable requirements for such internal controls established by the Comptroller General) of a certifying officer designated as provided in paragraph (1) of this subsection.

“(3) LIABILITY OF MEDICARE ADMINISTRATIVE CONTRACTOR.—No medicare administrative contractor shall be liable to the United States for a payment by a certifying or disbursing officer unless in connection with such payment or in the supervision of or selection of such officer the medicare administrative contractor acted with gross negligence.

“(4) LIMITATION ON CIVIL LIABILITY.—

“(A) IN GENERAL.—No medicare administrative contractor having a contract with the Secretary under this section, and no person employed by, or having a fiduciary relationship with, any such medicare administrative contractor or who furnishes professional services to such medicare administrative contractor, shall by reason of the performance of any duty, function, or activity required or authorized pursuant to this section or to a valid contract entered into under this section, be held civilly liable under any law of the United States or of any State (or political subdivision thereof) provided due care was exercised in the performance of such duty, function, or activity.

“(B) REIMBURSEMENT OF CERTAIN EXPENSES.—The Secretary shall make payment to a medicare administrative contractor under contract with the Secretary pursuant to this section, or to any member or employee thereof, or to any person who furnishes legal counsel or services to such medicare

administrative contractor, in an amount equal to the reasonable amount of the expenses incurred, as determined by the Secretary, in connection with the defense of any civil suit, action, or proceeding brought against such medicare administrative contractor or person related to the performance of any duty, function, or activity under such contract, provided due care was exercised in the performance of such duty, function, or activity.”

(2) CONSIDERATION OF INCORPORATION OF CURRENT LAW STANDARDS.—In developing contract performance requirements under section 1874A(b) of the Social Security Act, as inserted by paragraph (1), the Secretary shall consider inclusion of the performance standards described in sections 1816(f)(2) of such Act (relating to timely processing of reconsiderations and applications for exemptions) and section 1842(b)(2)(B) of such Act (relating to timely review of determinations and fair hearing requests), as such sections were in effect before the date of the enactment of this Act.

(b) CONFORMING AMENDMENTS TO SECTION 1816 (RELATING TO FISCAL INTERMEDIARIES).—Section 1816 (42 U.S.C. 1395h) is amended as follows:

(1) The heading is amended to read as follows:

“PROVISIONS RELATING TO THE ADMINISTRATION OF PART A”.

(2) Subsection (a) is amended to read as follows:

“(a) The administration of this part shall be conducted through contracts with medicare administrative contractors under section 1874A.”

(3) Subsection (b) is repealed.

(4) Subsection (c) is amended—

(A) by striking paragraph (1); and

(B) in each of paragraphs (2)(A) and (3)(A), by striking “agreement under this section” and inserting “contract under section 1874A that provides for making payments under this part”.

(5) Subsections (d) through (i) are repealed.

(6) Subsections (j) and (k) are each amended—

(A) by striking “An agreement with an agency or organization under this section” and inserting “A contract with a medicare administrative contractor under section 1874A with respect to the administration of this part”; and

(B) by striking “such agency or organization” and inserting “such medicare administrative contractor” each place it appears.

(7) Subsection (l) is repealed.

(c) CONFORMING AMENDMENTS TO SECTION 1842 (RELATING TO CARRIERS).—Section 1842 (42 U.S.C. 1395u) is amended as follows:

(1) The heading is amended to read as follows:

“PROVISIONS RELATING TO THE ADMINISTRATION OF PART B”.

(2) Subsection (a) is amended to read as follows:

“(a) The administration of this part shall be conducted through contracts with medicare administrative contractors under section 1874A.”

(3) Subsection (b) is amended—

(A) by striking paragraph (1);

(B) in paragraph (2)—

(i) by striking subparagraphs (A) and (B);

(ii) in subparagraph (C), by striking “carriers” and inserting “medicare administrative contractors”; and

(iii) by striking subparagraphs (D) and (E);

(C) in paragraph (3)—

(i) in the matter before subparagraph (A), by striking “Each such contract shall provide that the carrier” and inserting “The Secretary”;

(ii) by striking “will” the first place it appears in each of subparagraphs (A), (B), (F), (G), (H), and (L) and inserting “shall”;

(iii) in subparagraph (B), in the matter before clause (i), by striking “to the policyholders and subscribers of the carrier” and inserting “to the policyholders and subscribers of the medicare administrative contractor”;

(iv) by striking subparagraphs (C), (D), and (E);

(v) in subparagraph (H)—

(I) by striking “if it makes determinations or payments with respect to physicians’ services,”; and

(II) by striking “carrier” and inserting “medicare administrative contractor”;

(vi) by striking subparagraph (I);

- (vii) in subparagraph (L), by striking the semicolon and inserting a period;
 - (viii) in the first sentence, after subparagraph (L), by striking “and shall contain” and all that follows through the period; and
 - (ix) in the seventh sentence, by inserting “medicare administrative contractor,” after “carrier,”; and
 - (D) by striking paragraph (5);
 - (E) in paragraph (6)(D)(iv), by striking “carrier” and inserting “medicare administrative contractor”; and
 - (F) in paragraph (7), by striking “the carrier” and inserting “the Secretary” each place it appears.
- (4) Subsection (c) is amended—
- (A) by striking paragraph (1);
 - (B) in paragraph (2), by striking “contract under this section which provides for the disbursement of funds, as described in subsection (a)(1)(B),” and inserting “contract under section 1874A that provides for making payments under this part”;
 - (C) in paragraph (3)(A), by striking “subsection (a)(1)(B)” and inserting “section 1874A(a)(3)(B)”;
 - (D) in paragraph (4), by striking “carrier” and inserting “medicare administrative contractor”;
 - (E) in paragraph (5), by striking “contract under this section which provides for the disbursement of funds, as described in subsection (a)(1)(B), shall require the carrier” and “carrier responses” and inserting “contract under section 1874A that provides for making payments under this part shall require the medicare administrative contractor” and “contractor responses”, respectively; and
 - (F) by striking paragraph (6).
- (5) Subsections (d), (e), and (f) are repealed.
- (6) Subsection (g) is amended by striking “carrier or carriers” and inserting “medicare administrative contractor or contractors”.
- (7) Subsection (h) is amended—
- (A) in paragraph (2)—
 - (i) by striking “Each carrier having an agreement with the Secretary under subsection (a)” and inserting “The Secretary”; and
 - (ii) by striking “Each such carrier” and inserting “The Secretary”;
 - (B) in paragraph (3)(A)—
 - (i) by striking “a carrier having an agreement with the Secretary under subsection (a)” and inserting “medicare administrative contractor having a contract under section 1874A that provides for making payments under this part”; and
 - (ii) by striking “such carrier” and inserting “such contractor”;
 - (C) in paragraph (3)(B)—
 - (i) by striking “a carrier” and inserting “a medicare administrative contractor” each place it appears; and
 - (ii) by striking “the carrier” and inserting “the contractor” each place it appears; and
 - (D) in paragraphs (5)(A) and (5)(B)(iii), by striking “carriers” and inserting “medicare administrative contractors” each place it appears.
- (8) Subsection (l) is amended—
- (A) in paragraph (1)(A)(iii), by striking “carrier” and inserting “medicare administrative contractor”; and
 - (B) in paragraph (2), by striking “carrier” and inserting “medicare administrative contractor”.
- (9) Subsection (p)(3)(A) is amended by striking “carrier” and inserting “medicare administrative contractor”.
- (10) Subsection (q)(1)(A) is amended by striking “carrier”.
- (d) EFFECTIVE DATE; TRANSITION RULE.—
- (1) EFFECTIVE DATE.—
 - (A) APPLICATION TO COMPETITIVELY BID CONTRACTS.—The amendments made by this section shall apply to contracts that are competitively bid on or after such date or dates (but not later than 2 years after the date of the enactment of this Act) as the Secretary specifies.
 - (B) CONSTRUCTION FOR CURRENT CONTRACTS.—Such amendments shall not apply to contracts in effect before the date specified under subparagraph (A) that continue to retain the terms and conditions in effect on such date until such date as the contract is let out for competitive bidding under such amendments.

(C) DEADLINE FOR COMPETITIVE BIDDING.—The Secretary shall provide for the letting by competitive bidding of all contracts for functions of medicare administrative contractors for annual contract periods that begin on or after October 1, 2008.

(2) GENERAL TRANSITION RULES.—The Secretary shall take such steps, consistent with paragraph (1)(B) and (1)(C), as are necessary to provide for an appropriate transition from contracts under section 1816 and section 1842 of the Social Security Act (42 U.S.C. 1395h, 1395u) to contracts under section 1874A, as added by subsection (a)(1).

(3) AUTHORIZING CONTINUATION OF MIP FUNCTIONS UNDER CURRENT CONTRACTS AND AGREEMENTS AND UNDER ROLLOVER CONTRACTS.—The provisions contained in the exception in section 1893(d)(2) of the Social Security Act (42 U.S.C. 1395ddd(d)(2)) shall continue to apply notwithstanding the amendments made by this section, and any reference in such provisions to an agreement or contract shall be deemed to include a contract under section 1874A of such Act, as inserted by subsection (a)(1), that continues the activities referred to in such provisions.

(e) REFERENCES.—On and after the effective date provided under subsection (d)(1), any reference to a fiscal intermediary or carrier under title XI or XVIII of the Social Security Act (or any regulation, manual instruction, interpretative rule, statement of policy, or guideline issued to carry out such titles) shall be deemed a reference to an appropriate medicare administrative contractor (as provided under section 1874A of the Social Security Act).

(f) SECRETARIAL SUBMISSION OF LEGISLATIVE PROPOSAL.—Not later than 6 months after the date of the enactment of this Act, the Secretary shall submit to the appropriate committees of Congress a legislative proposal providing for such technical and conforming amendments in the law as are required by the provisions of this section.

(g) REPORTS ON IMPLEMENTATION.—

(1) PROPOSAL FOR IMPLEMENTATION.—At least 1 year before the date the Secretary proposes to first implement the plan for implementation of the amendments made by this section, the Secretary shall submit a report to Congress and the Comptroller General of the United States that describes such plan. The Comptroller General shall conduct an evaluation of such plan and shall submit to Congress, not later than 6 months after the date the report is received, a report on such evaluation and shall include in such report such recommendations as the Comptroller General deems appropriate.

(2) STATUS OF IMPLEMENTATION.—The Secretary shall submit a report to Congress not later than October 1, 2006, that describes the status of implementation of such amendments and that includes a description of the following:

(A) The number of contracts that have been competitively bid as of such date.

(B) The distribution of functions among contracts and contractors.

(C) A timeline for complete transition to full competition.

(D) A detailed description of how the Secretary has modified oversight and management of medicare contractors to adapt to full competition.

SEC. 302. REQUIREMENTS FOR INFORMATION SECURITY.

(a) IN GENERAL.—Section 1874A, as added by section 301, is amended by adding at the end the following new subsection:

“(e) REQUIREMENTS FOR INFORMATION SECURITY.—

“(1) DEVELOPMENT OF INFORMATION SECURITY PROGRAM.—A medicare administrative contractor that performs the functions referred to in subparagraphs (A) and (B) of subsection (a)(4) (relating to determining and making payments) shall implement a contractor-wide information security program to provide information security for the operation and assets of the contractor with respect to such functions under this title. An information security program under this paragraph shall meet the requirements for information security programs imposed on Federal agencies under section 3534(b)(2) of title 44, United States Code (other than requirements under subparagraphs (B)(ii), (F)(iii), and (F)(iv) of such section).

“(2) INDEPENDENT AUDITS.—

“(A) PERFORMANCE OF ANNUAL EVALUATIONS.—Each year a medicare administrative contractor that performs the functions referred to in subparagraphs (A) and (B) of subsection (a)(4) (relating to determining and making payments) shall undergo an evaluation of the information security of the contractor with respect to such functions under this title. The evaluation shall—

“(i) be performed by an entity that meets such requirements for independence as the Inspector General of the Department of Health and Human Services may establish; and

“(ii) test the effectiveness of information security control techniques for an appropriate subset of the contractor’s information systems (as defined in section 3502(8) of title 44, United States Code) relating to such functions under this title and an assessment of compliance with the requirements of this subsection and related information security policies, procedures, standards and guidelines.

“(B) DEADLINE FOR INITIAL EVALUATION.—

“(i) NEW CONTRACTORS.—In the case of a medicare administrative contractor covered by this subsection that has not previously performed the functions referred to in subparagraphs (A) and (B) of subsection (a)(4) (relating to determining and making payments) as a fiscal intermediary or carrier under section 1816 or 1842, the first independent evaluation conducted pursuant subparagraph (A) shall be completed prior to commencing such functions.

“(ii) OTHER CONTRACTORS.—In the case of a medicare administrative contractor covered by this subsection that is not described in clause (i), the first independent evaluation conducted pursuant subparagraph (A) shall be completed within 1 year after the date the contractor commences functions referred to in clause (i) under this section.

“(C) REPORTS ON EVALUATIONS.—

“(i) TO THE INSPECTOR GENERAL.—The results of independent evaluations under subparagraph (A) shall be submitted promptly to the Inspector General of the Department of Health and Human Services.

“(ii) TO CONGRESS.—The Inspector General of Department of Health and Human Services shall submit to Congress annual reports on the results of such evaluations.”.

(b) APPLICATION OF REQUIREMENTS TO FISCAL INTERMEDIARIES AND CARRIERS.—

(1) IN GENERAL.—The provisions of section 1874A(e)(2) of the Social Security Act (other than subparagraph (B)), as added by subsection (a), shall apply to each fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative contractors under such provisions.

(2) DEADLINE FOR INITIAL EVALUATION.—In the case of such a fiscal intermediary or carrier with an agreement or contract under such respective section in effect as of the date of the enactment of this Act, the first evaluation under section 1874A(e)(2)(A) of the Social Security Act (as added by subsection (a)), pursuant to paragraph (1), shall be completed (and a report on the evaluation submitted to the Secretary) by not later than 1 year after such date.

TITLE IV—EDUCATION AND OUTREACH IMPROVEMENTS

SEC. 401. PROVIDER EDUCATION AND TECHNICAL ASSISTANCE.

(a) COORDINATION OF EDUCATION FUNDING.—

(1) IN GENERAL.—The Social Security Act is amended by inserting after section 1888 the following new section:

“PROVIDER EDUCATION AND TECHNICAL ASSISTANCE

“SEC. 1889. (a) COORDINATION OF EDUCATION FUNDING.—The Secretary shall coordinate the educational activities provided through medicare contractors (as defined in subsection (f), including under section 1893) in order to maximize the effectiveness of Federal education efforts for providers of services, physicians, practitioners, facilities, and suppliers.”.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on the date of the enactment of this Act.

(3) REPORT.—Not later than October 1, 2002, the Secretary shall submit to Congress a report that includes a description and evaluation of the steps taken to coordinate the funding of provider education under section 1889(a) of the Social Security Act, as added by paragraph (1).

(b) INCENTIVES TO IMPROVE CONTRACTOR PERFORMANCE.—

(1) IN GENERAL.—Section 1874A, as added by section 301(a)(1) and as amended by section 302, is amended by adding at the end the following new subsection:

“(f) INCENTIVES TO IMPROVE CONTRACTOR PERFORMANCE IN PROVIDER EDUCATION AND OUTREACH.—In order to give medicare administrative contractors an incentive to implement effective education and outreach programs for providers of services, physicians, practitioners, facilities, and suppliers, the Secretary shall implement, a methodology to measure the specific claims payment error rates of such contractors in the processing or reviewing of medicare claims.”.

(2) APPLICATION TO FISCAL INTERMEDIARIES AND CARRIERS.—The provisions of section 1874A(f) of the Social Security Act, as added by paragraph (1), shall apply to each fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative contractors under such provisions.

(3) REPORTS.—Not later than October 1, 2002—

(A) the Secretary shall submit to Congress a report that describes how the Secretary intends to use the methodology in assessing medicare contractor performance in implementing effective education and outreach programs, including whether to use such methodology as a basis for performance bonuses; and

(B) the Comptroller General of the United States shall submit to Congress and to the Secretary a report on the adequacy of such methodology and shall include in the report such recommendations as the Comptroller General determines appropriate with respect to the methodology.

(c) REQUIREMENT TO MAINTAIN INTERNET SITES.—

(1) IN GENERAL.—Section 1889, as added by subsection (a), is amended by adding at the end the following new subsection:

“(b) INTERNET SITES; FAQs.—The Secretary, and each medicare contractor insofar as it provides services (including claims processing) for providers of services, physicians, practitioners, facilities, or suppliers, shall maintain an Internet site which—

“(1) provides answers in an easily accessible format to frequently asked questions, and

“(2) includes all materials published by the Secretary or the contractor, respectively,

relating to such providers of services, physicians, practitioners, facilities, and suppliers under the programs under this title and title XI insofar as it relates to such programs.”.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on October 1, 2002.

(d) IMPROVED PROVIDER EDUCATION AND TRAINING.—

(1) INCREASED FUNDING FOR ENHANCED EDUCATION AND TRAINING THROUGH MEDICARE INTEGRITY PROGRAM.—Section 1817(k)(4) (42 U.S.C. 1395i(k)(4)) is amended—

(A) in subparagraph (A), by striking “, subject to subparagraph (B)” and inserting “and functions described in subparagraph (C)(ii), subject to subparagraphs (B) and (C)”;

(B) in subparagraph (B), by striking “The amount appropriated” and inserting “Subject to subparagraph (C), the amount appropriated”; and

(C) by adding at the end the following new subparagraph:

“(C) ENHANCED PROVIDER EDUCATION AND TRAINING.—

“(i) IN GENERAL.—In addition to the amount appropriated under subparagraph (B), the amount appropriated under subparagraph (A) for a fiscal year (beginning with fiscal year 2003) is increased by \$35,000,000.

“(ii) USE.—The funds made available under this subparagraph shall be used only to increase the conduct by medicare contractors of education and training of providers of services, physicians, practitioners, facilities, and suppliers regarding billing, coding, and other appropriate items and may also be used to improve the accuracy, consistency, and timeliness of contractor responses to written and phone inquiries from providers of services, physicians, practitioners, facilities, and suppliers.”.

(2) TAILORING EDUCATION AND TRAINING FOR SMALL PROVIDERS OR SUPPLIERS.—

(A) IN GENERAL.—Section 1889, as added by subsection (a) and as amended by subsection (c), is further amended by adding at the end the following new subsection:

“(c) TAILORING EDUCATION AND TRAINING ACTIVITIES FOR SMALL PROVIDERS OR SUPPLIERS.—

“(1) IN GENERAL.—Insofar as a medicare contractor conducts education and training activities, it shall take into consideration the special needs of small

providers of services or suppliers (as defined in paragraph (2)). Such education and training activities for small providers or services and suppliers may include the provision of technical assistance (such as review of billing systems and internal controls to determine program compliance and to suggest more efficient and effective means of achieving such compliance).

“(2) SMALL PROVIDER OF SERVICES OR SUPPLIER.—In this subsection, the term ‘small provider of services or supplier’ means—

“(A) an institutional provider of services with fewer than 25 full-time-equivalent employees; or

“(B) a physician, practitioner, facility, or supplier with fewer than 10 full-time-equivalent employees.”

(B) EFFECTIVE DATE.—The amendment made by subparagraph (A) shall take effect on October 1, 2002.

(e) ADDITIONAL PROVIDER EDUCATION PROVISIONS.—

(1) IN GENERAL.—Section 1889, as added by subsection (a) and as amended by subsections (c) and (d)(2), is further amended by adding at the end the following new subsections:

“(d) ENCOURAGEMENT OF PARTICIPATION IN EDUCATION PROGRAM ACTIVITIES.—A medicare contractor may not use a record of attendance at (or failure to attend) educational activities or other information gathered during an educational program conducted under this section or otherwise by the Secretary to select or track providers of services, physicians, practitioners, facilities, or suppliers for the purpose of conducting any type of audit or prepayment review.

“(e) CONSTRUCTION.—Nothing in this section or section 1893(g) shall be construed as providing for disclosure by a medicare contractor of information that would compromise pending law enforcement activities or reveal findings of law enforcement-related audits.

“(f) DEFINITIONS.—For purposes of this section and section 1817(k)(4)(C), the term ‘medicare contractor’ includes the following:

“(1) A medicare administrative contractor with a contract under section 1874A, a fiscal intermediary with a contract under section 1816, and a carrier with a contract under section 1842.

“(2) An eligible entity with a contract under section 1893.

Such term does not include, with respect to activities of a specific provider of services, physician, practitioner, facility, or supplier an entity that has no authority under this title or title XI with respect to such activities and such provider of services, physician, practitioner, facility, or supplier.”

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on the date of the enactment of this Act.

SEC. 402. ACCESS TO AND PROMPT RESPONSES FROM MEDICARE ADMINISTRATIVE CONTRACTORS.

(a) IN GENERAL.—Section 1874A, as added by section 301 and as amended by sections 302 and 401(b)(1), is further amended by adding at the end the following new subsection:

“(g) COMMUNICATIONS WITH BENEFICIARIES, PROVIDERS OF SERVICES, PHYSICIANS, PRACTITIONERS, FACILITIES, AND SUPPLIERS.—

“(1) COMMUNICATION STRATEGY.—The Secretary shall develop a strategy for communications with beneficiaries and with providers of services, physicians, practitioners, facilities, and suppliers under this title.

“(2) RESPONSE TO WRITTEN INQUIRIES.—Each medicare administrative contractor shall, for those providers of services, physicians, practitioners, facilities, and suppliers which submit claims to the contractor for claims processing and for those beneficiaries with respect to which claims are submitted for claims processing, provide general written responses (which may be through electronic transmission) in a clear, concise, and accurate manner to inquiries by beneficiaries, providers of services, physicians, practitioners, facilities, and suppliers concerning the programs under this title within 45 business days of the date of receipt of such inquiries.

“(3) RESPONSE TO TOLL-FREE LINES.—Each medicare administrative contractor shall, for those providers of services, physicians, practitioners, facilities, and suppliers which submit claims to the contractor for claims processing and for those beneficiaries with respect to which claims are submitted for claims processing, maintain a toll-free telephone number at which beneficiaries, providers, physicians, practitioners, facilities, and suppliers may obtain information regarding billing, coding, claims, coverage, and other appropriate information under this title.

“(4) MONITORING OF CONTRACTOR RESPONSES.—

“(A) IN GENERAL.—Each medicare administrative contractor shall, consistent with standards developed by the Secretary under subparagraph (B)—

“(i) maintain a system for identifying who provides the information referred to in paragraphs (2) and (3); and

“(ii) monitor the accuracy, consistency, and timeliness of the information so provided.

“(B) DEVELOPMENT OF STANDARDS.—

“(i) IN GENERAL.—The Secretary shall establish (and publish in the Federal Register) standards to monitor the accuracy, consistency, and timeliness of the information provided in response to written and telephone inquiries under this subsection. Such standards shall be consistent with the performance requirements established under subsection (b)(3).

“(ii) EVALUATION.—In conducting evaluations of individual medicare administrative contractors, the Secretary shall take into account the results of the monitoring conducted under subparagraph (A) taking into account as performance requirements the standards established under clause (i).

“(C) DIRECT MONITORING.—Nothing in this paragraph shall be construed as preventing the Secretary from directly monitoring the accuracy, consistency, and timeliness of the information so provided.”.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect October 1, 2002.

(c) APPLICATION TO FISCAL INTERMEDIARIES AND CARRIERS.—The provisions of section 1874A(g) of the Social Security Act, as added by subsection (a), shall apply to each fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative contractors under such provisions.

SEC. 403. RELIANCE ON GUIDANCE.

(a) IN GENERAL.—Section 1871(e), as added by section 102(a), is further amended by adding at the end the following new paragraph:

“(2) If—

“(A) a provider of services, physician, practitioner, facility, or supplier follows written guidance (which may have been transmitted electronically) provided—

“(i) by the Secretary; or

“(ii) by a medicare contractor (as defined in section 1889(f) and whether in the form of a written response to a written inquiry under section 1874A(g)(1) or otherwise) acting within the scope of the contractor’s contract authority,

in response to a written inquiry with respect to the furnishing of an item or service or the submission of a claim for benefits for such an item or service;

“(B) the Secretary determines that—

“(i) the provider of services, physician, practitioner, facility, or supplier has accurately presented the circumstances relating to such item, service, and claim to the Secretary or the contractor in the written guidance; and

“(ii) there is no indication of fraud or abuse committed by the provider of services, physician, practitioner, facility, or supplier against the program under this title; and

“(C) the guidance was in error;

the provider of services, physician, practitioner, facility, or supplier shall not be subject to any penalty or interest (relating to an overpayment, if any) under this title (or the provisions of title XI insofar as they relate to this title) relating to the provision of such item or service or such claim if the provider of services, physician, practitioner, facility, or supplier reasonably relied on such guidance. In applying this paragraph with respect to guidance in the form of general responses to frequently asked questions, the Secretary retains authority to determine the extent to which such general responses apply to the particular circumstances of individual claims. Nothing in this paragraph shall be construed as affecting the application of section 1870(c) (relating to no adjustment in the cases of certain overpayments).”.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to penalties imposed on or after the date of the enactment of this Act.

SEC. 404. FACILITATION OF CONSISTENT INFORMATION TO PROVIDERS.

The Secretary shall appoint an individual within the Department of Health and Human Services who shall be responsible—

(1) for responding to complaints and grievances from providers of services, physicians, practitioners, facilities, and suppliers under the medicare program

under title XVIII of the Social Security Act (including provisions of title XI of the Social Security Act insofar as they relate to such title XVIII and are not administered by the Office of the Inspector General of the Department of Health and Human Services) concerning inconsistent information or inconsistent responses provided under such program; and

(2) in so responding, for facilitating an appropriate response from the Department of Health and Human Services or from appropriate medicare contractors. Such individual shall not serve as an advocate for any specific policy within the Department.

SEC. 405. POLICY DEVELOPMENT REGARDING EVALUATION AND MANAGEMENT (E & M) DOCUMENTATION GUIDELINES.

(a) **IN GENERAL.**—The Secretary may not implement any new documentation guidelines for evaluation and management physician services under the title XVIII of the Social Security Act on or after the date of the enactment of this Act unless the Secretary—

(1) has developed the guidelines in collaboration with practicing physicians (including both generalists and specialists) and provided for an assessment of the proposed guidelines by the physician community;

(2) has established a plan that contains specific goals, including a schedule, for improving the use of such guidelines;

(3) has conducted appropriate and representative pilot projects under subsection (b) to test the evaluation and management documentation guidelines;

(4) finds that the objectives described in subsection (c) will be met in the implementation of such guidelines; and

(5) has established, and is implementing, a program to educate physicians on the use of such guidelines.

The Secretary may make changes to the manner in which existing evaluation and management documentation guidelines are implemented to reduce paperwork burdens on physicians.

(b) **PILOT PROJECTS TO TEST EVALUATION AND MANAGEMENT DOCUMENTATION GUIDELINES.**—

(1) **IN GENERAL.**—The Secretary shall conduct under this subsection appropriate and representative pilot projects to test new evaluation and management documentation guidelines referred to in subsection (a).

(2) **LENGTH AND CONSULTATION.**—Each pilot project under this subsection shall—

(A) be voluntary;

(B) be of sufficient length as determined by the Secretary to allow for preparatory physician and medicare contractor education, analysis, and use and assessment of potential evaluation and management guidelines; and

(C) be conducted, in development and throughout the planning and operational stages of the project, in consultation with practicing physicians (including both generalists and specialists).

(3) **RANGE OF PILOT PROJECTS.**—Of the pilot projects conducted under this subsection—

(A) at least one shall focus on a peer review method by physicians (not employed by a medicare contractor) which evaluates medical record information for claims submitted by physicians identified as statistical outliers relative to definitions published in the Current Procedures Terminology (CPT) code book of the American Medical Association;

(B) at least one shall focus on an alternative method to detailed guidelines based on physician documentation of face to face encounter time with a patient;

(C) at least one shall be conducted for services furnished in a rural area and at least one for services furnished outside such an area; and

(D) at least one shall be conducted in a setting where physicians bill under physicians services in teaching settings and at least one shall be conducted in a setting other than a teaching setting.

(4) **BANNING OF TARGETING OF PILOT PROJECT PARTICIPANTS.**—Data collected under this subsection shall not be used as the basis for overpayment demands or post-payment audits. Such limitation applies only to claims filed as part of the pilot project and lasts only for the duration of the pilot project and only as long as the provider is a participant in the pilot project.

(5) **STUDY OF IMPACT.**—Each pilot project shall examine the effect of the new evaluation and management documentation guidelines on—

(A) different types of physician practices, including those with fewer than 10 full-time-equivalent employees (including physicians); and

(B) the costs of physician compliance, including education, implementation, auditing, and monitoring.

- (6) PERIODIC REPORTS.—The Secretary shall submit to Congress periodic reports on the pilot projects under this subsection.
- (c) OBJECTIVES FOR EVALUATION AND MANAGEMENT GUIDELINES.—The objectives for new evaluation and management documentation guidelines developed by the Secretary shall be to—
- (1) identify clinically relevant documentation needed to code accurately and assess coding levels accurately;
 - (2) decrease the level of non-clinically pertinent and burdensome documentation time and content in the physician's medical record;
 - (3) increase accuracy by reviewers; and
 - (4) educate both physicians and reviewers.
- (d) DEFINITIONS.—In this section—
- (1) the term "rural area" has the meaning given that term in section 1886(d)(2)(D) of the Social Security Act, 42 U.S.C. 1395ww(d)(2)(D); and
 - (2) the term "teaching settings" are those settings described in section 415.150 of title 42, Code of Federal Regulations.

SEC. 406. BENEFICIARY OUTREACH DEMONSTRATION PROGRAM; REPORT ON 1-800 MEDICARE NUMBER.

- (a) BENEFICIARY OUTREACH DEMONSTRATION PROGRAM.—
- (1) IN GENERAL.—The Secretary shall establish a demonstration program (in this subsection referred to as the "demonstration program") under which medicare specialists employed by the Department of Health and Human Services provide advice and assistance to medicare beneficiaries at the location of existing local offices of the Social Security Administration.
 - (2) LOCATIONS.—
 - (A) IN GENERAL.—The demonstration program shall be conducted in at least 6 offices or areas. Subject to subparagraph (B), in selecting such offices and areas, the Secretary shall provide preference for offices with a high volume of visits by medicare beneficiaries.
 - (B) ASSISTANCE FOR RURAL BENEFICIARIES.—The Secretary shall provide for the selection of at least 2 rural areas to participate in the demonstration program. In conducting the demonstration program in such rural areas, the Secretary shall provide for medicare specialists to travel among local offices in a rural area on a scheduled basis.
 - (3) DURATION.—The demonstration program shall be conducted over a 3-year period.
 - (4) EVALUATION AND REPORT.—
 - (A) EVALUATION.—The Secretary shall provide for an evaluation of the demonstration program. Such evaluation shall include an analysis of—
 - (i) utilization of, and beneficiary satisfaction with, the assistance provided under the program; and
 - (ii) the cost-effectiveness of providing beneficiary assistance through out-stationing medicare specialists at local offices of the Social Security Administration.
 - (B) REPORT.—The Secretary shall submit to Congress a report on such evaluation and shall include in such report recommendations regarding the feasibility of permanently out-stationing medicare specialists at local offices of the Social Security Administration.
- (b) REPORT ON 1-800 MEDICARE NUMBER.—
- (1) STUDY.—The Comptroller General of the United States shall conduct a study to monitor the accuracy and consistency of information provided to medicare beneficiaries through the toll-free 1-800 Medicare Number, including an assessment of whether the information provided is sufficient to answer beneficiary questions. In conducting the study, the Comptroller General shall examine the education and training of the individuals providing information through the 1-800 Medicare Number.
 - (2) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1).

SEC. 407. PROVIDER ENROLLMENT APPLICATIONS.

- (a) DEADLINES AND MONITORING.—Section 1871 (42 U.S.C. 1395hh), as amended by sections 101(a), 102, and 103, is further amended by adding at the end the following new subsection:
- "(g)(1)(A) The Secretary shall establish by regulation procedures under which there are deadlines for actions on applications for enrollment (and, if applicable, renewal of enrollment).
- "(B) The Secretary shall monitor the performance of medicare administrative contractors in meeting the deadlines established under subparagraph (A)."

(b) CONSULTATION BEFORE CHANGING PROVIDER ENROLLMENT FORMS.—

(1) IN GENERAL.—Section 1871(g) (42 U.S.C. 1395hh(g)), as added by subsection (a), is amended by adding at the end the following new paragraph:

“(2) The Secretary shall consult with providers of services, physicians, practitioners, facilities, and suppliers before making changes in the provider enrollment forms required of such providers, physicians, practitioners, facilities, and suppliers to be eligible to submit claims for which payment may be made under this title.”.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply with respect to changes in provider enrollment forms made on or after January 1, 2002.

TITLE V—REVIEW, RECOVERY, AND ENFORCEMENT REFORM

SEC. 501. PREPAYMENT REVIEW.

(a) IN GENERAL.—Section 1874A, as added by section 301 and as amended by sections 302, 401(b)(1), and 402, is further amended by adding at the end the following new subsection:

“(h) CONDUCT OF PREPAYMENT REVIEW.—

“(1) STANDARDIZATION OF RANDOM PREPAYMENT REVIEW.—If a medicare administrative contractor conducts a random prepayment review, the contractor may only conduct such review in accordance with a standard protocol for random prepayment audits developed by the Secretary.

“(2) LIMITATIONS ON INITIATION OF NON-RANDOM PREPAYMENT REVIEW.—A medicare administrative contractor may not initiate non-random prepayment review of a provider of services, physician, practitioner, facility, or supplier based on the initial identification by that provider of services, physician, practitioner, facility, or supplier of an improper billing practice unless there is a likelihood of sustained or high level of payment error (as defined by the Secretary).

“(3) TERMINATION OF NON-RANDOM PREPAYMENT REVIEW.—The Secretary shall issue regulations relating to the termination, including termination dates, of non-random prepayment review. Such regulations may vary such a termination date based upon the differences in the circumstances triggering prepayment review.

“(4) CONSTRUCTION.—Nothing in this subsection shall be construed as preventing the denial of payments for claims actually reviewed under a random prepayment review. In the case of a provider of services, physician, practitioner, facility, or supplier with respect to which amounts were previously overpaid, nothing in this subsection shall be construed as limiting the ability of a medicare administrative contractor to request the periodic production of records or supporting documentation for a limited sample of submitted claims to ensure that the previous practice is not continuing.

“(5) RANDOM PREPAYMENT REVIEW DEFINED.—For purposes of this subsection, the term ‘random prepayment review’ means a demand for the production of records or documentation absent cause with respect to a claim.”.

(b) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided in this subsection, the amendment made by subsection (a) shall take effect on the date of the enactment of this Act.

(2) DEADLINE FOR PROMULGATION OF CERTAIN REGULATIONS.—The Secretary shall first issue regulations under section 1874A(h) of the Social Security Act, as added by subsection (a), by not later than 1 year after the date of the enactment of this Act.

(3) APPLICATION OF STANDARD PROTOCOLS FOR RANDOM PREPAYMENT REVIEW.—Section 1874A(h)(1) of the Social Security Act, as added by subsection (a), shall apply to random prepayment reviews conducted on or after such date (not later than 1 year after the date of the enactment of this Act) as the Secretary shall specify.

(c) APPLICATION TO FISCAL INTERMEDIARIES AND CARRIERS.—The provisions of section 1874A(h) of the Social Security Act, as added by subsection (a), shall apply to each fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative contractors under such provisions.

SEC. 502. RECOVERY OF OVERPAYMENTS.

(a) IN GENERAL.—Section 1874A, as added by section 301 and as amended by sections 302, 401(b)(1), 402, and 501(a), is further amended by adding at the end the following new subsection:

“(i) RECOVERY OF OVERPAYMENTS.—

“(1) USE OF REPAYMENT PLANS.—

“(A) IN GENERAL.—If the repayment, within the period otherwise permitted by a provider of services, physician, practitioner, facility, or supplier, of an overpayment under this title meets the standards developed under subparagraph (B), subject to subparagraph (C), and the provider, physician, practitioner, facility, or supplier requests the Secretary to enter into a repayment plan with respect to such overpayment, the Secretary shall enter into a plan with the provider, physician, practitioner, facility, or supplier for the offset or repayment (at the election of the provider, physician, practitioner, facility, or supplier) of such overpayment over a period of at least one year, but not longer than 3 years. Interest shall accrue on the balance through the period of repayment. The repayment plan shall meet terms and conditions determined to be appropriate by the Secretary.

“(B) DEVELOPMENT OF STANDARDS.—The Secretary shall develop standards for the recovery of overpayments. Such standards shall—

“(i) include a requirement that the Secretary take into account (and weigh in favor of the use of a repayment plan) the reliance (as described in section 1871(e)(2)) by a provider of services, physician, practitioner, facility, and supplier on guidance when determining whether a repayment plan should be offered; and

“(ii) provide for consideration of the financial hardship imposed on a provider of services, physician, practitioner, facility, or supplier in considering such a repayment plan.

In developing standards with regard to financial hardship with respect to a provider of services, physician, practitioner, facility, or supplier, the Secretary shall take into account the amount of the proposed recovery as a proportion of payments made to that provider, physician, practitioner, facility, or supplier.

“(C) EXCEPTIONS.—Subparagraph (A) shall not apply if—

“(i) the Secretary has reason to suspect that the provider of services, physician, practitioner, facility, or supplier may file for bankruptcy or otherwise cease to do business or discontinue participation in the program under this title; or

“(ii) there is an indication of fraud or abuse committed against the program.

“(D) IMMEDIATE COLLECTION IF VIOLATION OF REPAYMENT PLAN.—If a provider of services, physician, practitioner, facility, or supplier fails to make a payment in accordance with a repayment plan under this paragraph, the Secretary may immediately seek to offset or otherwise recover the total balance outstanding (including applicable interest) under the repayment plan.

“(E) RELATION TO NO FAULT PROVISION.—Nothing in this paragraph shall be construed as affecting the application of section 1870(c) (relating to no adjustment in the cases of certain overpayments).

“(2) LIMITATION ON RECOUPMENT.—

“(A) NO RECOUPMENT UNTIL RECONSIDERATION EXERCISED.—In the case of a provider of services, physician, practitioner, facility, or supplier that is determined to have received an overpayment under this title and that seeks a reconsideration by a qualified independent contractor on such determination under section 1869(b)(1), the Secretary may not take any action (or authorize any other person, including any medicare contractor, as defined in subparagraph (C)) to recoup the overpayment until the date the decision on the reconsideration has been rendered. If the provisions of section 1869(b)(1) (providing for such a reconsideration by a qualified independent contractor) are not in effect, in applying the previous sentence any reference to such a reconsideration shall be treated as a reference to a redetermination by the fiscal intermediary or carrier involved.

“(B) PAYMENT OF INTEREST.—

“(i) RETURN OF RECOUPED AMOUNT WITH INTEREST IN CASE OF REVERSAL.—Insofar as such determination on appeal against the provider of services, physician, practitioner, facility, or supplier is later reversed, the Secretary shall provide for repayment of the amount recouped plus interest for the period in which the amount was recouped.

“(ii) INTEREST IN CASE OF AFFIRMATION.—Insofar as the determination on such appeal is against the provider of services, physician, prac-

tion, facility, or supplier, interest on the overpayment shall accrue on and after the date of the original notice of overpayment.

“(iii) RATE OF INTEREST.—The rate of interest under this subparagraph shall be the rate otherwise applicable under this title in the case of overpayments.

“(C) MEDICARE CONTRACTOR DEFINED.—For purposes of this subsection, the term ‘medicare contractor’ has the meaning given such term in section 1889(f).

“(3) PAYMENT AUDITS.—

“(A) WRITTEN NOTICE FOR POST-PAYMENT AUDITS.—Subject to subparagraph (C), if a medicare contractor decides to conduct a post-payment audit of a provider of services, physician, practitioner, facility, or supplier under this title, the contractor shall provide the provider of services, physician, practitioner, facility, or supplier with written notice (which may be in electronic form) of the intent to conduct such an audit.

“(B) EXPLANATION OF FINDINGS FOR ALL AUDITS.—Subject to subparagraph (C), if a medicare contractor audits a provider of services, physician, practitioner, facility, or supplier under this title, the contractor shall—

“(i) give the provider of services, physician, practitioner, facility, or supplier a full review and explanation of the findings of the audit in a manner that is understandable to the provider of services, physician, practitioner, facility, or supplier and permits the development of an appropriate corrective action plan;

“(ii) inform the provider of services, physician, practitioner, facility, or supplier of the appeal rights under this title as well as consent settlement options (which are at the discretion of the Secretary);

“(iii) give the provider of services, physician, practitioner, facility, or supplier an opportunity to provide additional information to the contractor; and

“(iv) take into account information provided, on a timely basis, by the provider of services, physician, practitioner, facility, or supplier under clause (iii).

“(C) EXCEPTION.—Subparagraphs (A) and (B) shall not apply if the provision of notice or findings would compromise pending law enforcement activities, whether civil or criminal, or reveal findings of law enforcement-related audits.

“(4) NOTICE OF OVER-UTILIZATION OF CODES.—The Secretary shall establish, in consultation with organizations representing the classes of providers of services, physicians, practitioners, facilities, and suppliers, a process under which the Secretary provides for notice to classes of providers of services, physicians, practitioners, facilities, and suppliers served by a medicare contractor in cases in which the contractor has identified that particular billing codes may be overutilized by that class of providers of services, physicians, practitioners, facilities, or suppliers under the programs under this title (or provisions of title XI insofar as they relate to such programs).

“(5) STANDARD METHODOLOGY FOR PROBE SAMPLING.—The Secretary shall establish a standard methodology for medicare contractors to use in selecting a sample of claims for review in the case of an abnormal billing pattern.

“(6) CONSENT SETTLEMENT REFORMS.—

“(A) IN GENERAL.—The Secretary may use a consent settlement (as defined in subparagraph (D)) to settle a projected overpayment.

“(B) OPPORTUNITY TO SUBMIT ADDITIONAL INFORMATION BEFORE CONSENT SETTLEMENT OFFER.—Before offering a provider of services, physician, practitioner, facility, or supplier a consent settlement, the Secretary shall—

“(i) communicate to the provider of services, physician, practitioner, facility, or supplier in a non-threatening manner—

“(I) that, based on a review of the medical records requested by the Secretary, a preliminary evaluation of those records indicates that there would be an overpayment;

“(II) the nature of the problems identified in such evaluation; and

“(III) the steps that the provider of services, physician, practitioner, facility, or supplier should take to address the problems; and

“(ii) provide for a 45-day period during which the provider of services, physician, practitioner, facility, or supplier may furnish additional information concerning the medical records for the claims that had been reviewed.

“(C) CONSENT SETTLEMENT OFFER.—The Secretary shall review any additional information furnished by the provider of services, physician, practitioner, facility, or supplier under subparagraph (B)(ii). Taking into consideration such information, the Secretary shall determine if there still appears to be an overpayment. If so, the Secretary—

“(i) shall provide notice of such determination to the provider of services, physician, practitioner, facility, or supplier, including an explanation of the reason for such determination; and

“(ii) in order to resolve the overpayment, may offer the provider of services, physician, practitioner, facility, or supplier—

“(I) the opportunity for a statistically valid random sample; or

“(II) a consent settlement.

The opportunity provided under clause (ii)(I) does not waive any appeal rights with respect to the alleged overpayment involved.

“(D) CONSENT SETTLEMENT DEFINED.—For purposes of this paragraph, the term ‘consent settlement’ means an agreement between the Secretary and a provider of services, physician, practitioner, facility, or supplier whereby both parties agree to settle a projected overpayment based on less than a statistically valid sample of claims and the provider of services, physician, practitioner, facility, or supplier agrees not to appeal the claims involved.

“(7) LIMITATION ON USE OF EXTRAPOLATION.—A medicare contractor may not use extrapolation to determine overpayment amounts to be recovered by recoupment, offset, or otherwise unless—

“(A) there is a sustained or high level of payment error (as defined by the Secretary by regulation); or

“(B) documented educational intervention has failed to correct the payment error (as determined by the Secretary).”.

(b) EFFECTIVE DATES AND DEADLINES.—

(1) Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services shall first—

(A) develop standards for the recovery of overpayments under section 1874A(i)(1)(B) of the Social Security Act, as added by subsection (a);

(B) establish the process for notice of overutilization of billing codes under section 1874A(i)(4) of the Social Security Act, as added by subsection (a); and

(C) establish a standard methodology for selection of sample claims for abnormal billing patterns under section 1874A(i)(5) of the Social Security Act, as added by subsection (a).

(2) Section 1874A(i)(2) of the Social Security Act, as added by subsection (a), shall apply to actions taken after the date of the enactment of this Act.

(3) Section 1874A(i)(3) of the Social Security Act, as added by subsection (a), shall apply to audits initiated after the date of the enactment of this Act.

(4) Section 1874A(i)(6) of the Social Security Act, as added by subsection (a), shall apply to consent settlements entered into after the date of the enactment of this Act.

(5) Section 1874A(i)(7) of the Social Security Act, as added by subsection (a), shall apply to statistically valid random samples initiated after the date of the enactment of this Act.

SEC. 503. PROCESS FOR CORRECTION OF MINOR ERRORS AND OMISSIONS ON CLAIMS WITHOUT PURSUING APPEALS PROCESS.

(a) IN GENERAL.—The Secretary shall develop, in consultation with appropriate medicare contractors (as defined in section 1889(f) of the Social Security Act, as added by section 401(e)(1)) and representatives of providers of services, physicians, practitioners, facilities, and suppliers, a process whereby, in the case of minor errors or omissions (as defined by the Secretary) that are detected in the submission of claims under the programs under title XVIII of such Act, a provider of services, physician, practitioner, facility, or supplier is given an opportunity to correct such an error or omission without the need to initiate an appeal. Such process shall include the ability to resubmit corrected claims.

(b) DEADLINE.—Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services shall first develop the process under subsection (a).

SEC. 504. PROGRAM AND PAYMENT EXCLUSIONS.

(a) AUTHORITY TO WAIVE A PROGRAM EXCLUSION.—The first sentence of section 1128(c)(3)(B) (42 U.S.C. 1320a–7(c)(3)(B)) is amended to read as follows: “Subject to subparagraph (G), in the case of an exclusion under subsection (a), the minimum period of exclusion shall be not less than five years, except that, upon the request of the administrator of a Federal health care program (as defined in section

1128B(f) who determines that the exclusion would impose a hardship on beneficiaries under that program, the Secretary may waive the exclusion under subsection (a)(1), (a)(3), or (a)(4) with respect to that program in the case of an individual or entity that is the sole community physician or sole source of essential specialized services in a community.”

(b) EXCEPTION FOR CERTAIN PAYMENT EXCLUSIONS.—

(1) IN GENERAL.—Section 1862(a)(11) (42 U.S.C. 1395y(a)(11)) is amended—

(A) by inserting “(other than a child)” after “immediate relatives”; and

(B) by inserting before the semicolon the following; “, unless the items or services are furnished in a rural area (as defined in section 1886(d)(2)(D))”.

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to items and services furnished on or after January 1, 2003.

TITLE VI—EMTALA IMPROVEMENTS

SEC. 601. PAYMENT FOR EMTALA-MANDATED SCREENING AND STABILIZATION SERVICES.

(a) IN GENERAL.—Section 1862 (42 U.S.C. 1395y) is amended by inserting after subsection (c) the following new subsection:

“(d) For purposes of subsection (a)(1)(A), in the case of any item or service that is required to be provided pursuant to section 1867 to an individual who is entitled to benefits under this title, determinations as to whether the item or service is reasonable and necessary shall be made on the basis of the information available to the treating physician or practitioner (including the patient’s presenting symptoms or complaint) at the time the item or service was ordered or furnished by the physician or practitioner (and not on the patient’s principal diagnosis). When making such determinations with respect to such an item or service, the Secretary shall not consider the frequency with which the item or service was provided to the patient before or after the time of the admission or visit.”

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to items and services furnished on or after January 1, 2002.

SEC. 602. EMERGENCY MEDICAL TREATMENT AND ACTIVE LABOR ACT (EMTALA) TASK FORCE.

(a) ESTABLISHMENT.—There is established within the Department of Health and Human Services the Emergency Medical Treatment and Active Labor Act (EMTALA) Task Force (in this section referred to as the “Task Force”). In this section, the term “EMTALA” refers to the provisions of section 1867 of the Social Security Act (42 U.S.C. 1395dd).

(b) MEMBERSHIP.—The Task Force shall be composed of 22 members as follows:

(1) The Administrator of the Centers for Medicare & Medicaid Services.

(2) The Inspector General of the Department of Health and Human Services.

(3) 5 individuals selected by such Administrator—

(A) 4 of whom are staff at regional offices of such Centers involved in investigations of violations of EMTALA, and 1 each from the Northeastern Consortium, Midwestern Consortium, Southern Consortium, and Western Consortium; and

(B) 1 of whom is involved in EMTALA policy at the national level.

(4) 2 individuals who participate in peer review organizations’ review of EMTALA determinations.

(5) 4 hospital administrators who have experience with the application of EMTALA.

(6) 8 practicing physicians who have experience with the application of EMTALA, of whom—

(A) 2 are practicing physicians in the field of emergency medicine;

(B) 1 is a practicing physician in the field of general surgery;

(C) 1 is a practicing physician in the field of orthopedic surgery;

(D) 1 is a practicing physician in the field of neurosurgery;

(E) 1 is a practicing physician in the field of ophthalmology;

(F) 1 is a practicing physician in the field of obstetrics and gynecology;

and

(G) 1 is a practicing physician in the field of psychiatry.

(7) 1 who is a representative of consumers.

(8) 1 practicing defense attorney specializing in EMTALA defense cases.

The Administrator of the Centers for Medicare & Medicaid Services shall select the members described in paragraphs (3) through (8) and shall provide special consideration to qualified individuals nominated by organizations in the relevant areas of specialty.

(c) GENERAL RESPONSIBILITIES.—The Task Force—

- (1) shall review EMTALA regulations;
 - (2) shall provide advice and recommendations to the Secretary of Health and Human Services with respect to those regulations and their application to hospitals and physicians;
 - (3) shall solicit comments and recommendations from hospitals, physicians, and the public regarding the implementation of such regulations; and
 - (4) may disseminate information on the application of such regulations to hospitals, physicians, and the public.
- (d) ADMINISTRATIVE MATTERS.—
- (1) CHAIRPERSON.—The members of the Task Force shall elect a member to serve as chairperson of the Task Force for the life of the Task Force.
 - (2) MEETINGS.—The Task Force shall first meet at the direction of the Secretary. The Task Force shall then meet twice per year and at such other times as the Task Force may provide.
- (e) TERMINATION.—The Task Force shall terminate 3 years after the date of its first meeting.
- (f) EXEMPTION FROM ADVISORY COMMITTEE ACT.—The Task Force shall be exempt from the Federal Advisory Committee Act.

SEC. 603. NOTIFICATION OF PROVIDERS WHEN EMTALA INVESTIGATION CLOSED.

Section 1867(d) (42 U.S.C. 42 U.S.C. 1395dd(d)) is amended by adding at the end the following new paragraph:

“(4) NOTICE UPON CLOSING AN INVESTIGATION.—The Secretary shall establish a procedure to notify hospitals and physicians when an investigation under this section is closed.”.

SEC. 604. PRIOR REVIEW BY PEER REVIEW ORGANIZATIONS IN EMTALA CASES INVOLVING TERMINATION OF PARTICIPATION.

- (a) IN GENERAL.—Section 1867(d)(3) (42 U.S.C. 1395dd(d)(3)) is amended—
- (1) in the first sentence, by inserting “or in terminating a hospital’s participation under this title” after “in imposing sanctions under paragraph (1)”; and
 - (2) by adding at the end the following new sentences: “Except in the case in which a delay would jeopardize the health or safety of individuals, the Secretary shall also request such a review before making a compliance determination as part of the process of terminating a hospital’s participation under this title for violations related to the appropriateness of a medical screening examination, stabilizing treatment, or an appropriate transfer as required by this section, and shall provide a period of 5 business days for such review. The organization shall provide a copy of the report on its findings to the hospital or physician consistent with confidentiality requirements imposed on the organization under such part B.”.
- (b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to terminations of participation initiated on or after the date of the enactment of this Act.

TITLE VII—MISCELLANEOUS IMPROVEMENTS

SEC. 701. METHODS FOR DETERMINING PAYMENT BASIS FOR NEW LAB TESTS.

Section 1833(h) (42 U.S.C. 1395l(h)) is amended by adding at the end the following:

“(8)(A) The Secretary shall establish by regulation procedures for determining the basis for, and amount of, payment under this subsection for any clinical diagnostic laboratory test with respect to which a new or substantially revised HCPCS code is assigned on or after January 1, 2003 (in this paragraph referred to as ‘new tests’).”

“(B) Determinations under subparagraph (A) shall be made only after the Secretary—

“(i) makes available to the public (through an Internet site and other appropriate mechanisms) a list that includes any such test for which establishment of a payment amount under this subsection is being considered for a year;

“(ii) on the same day such list is made available, causes to have published in the Federal Register notice of a meeting to receive comments and recommendations (and data on which recommendations are based) from the public on the appropriate basis under this subsection for establishing payment amounts for the tests on such list;

“(iii) not less than 30 days after publication of such notice convenes a meeting, that includes representatives of officials of the Centers for Medicare & Medicaid Services involved in determining payment amounts, to receive such comments and recommendations (and data on which the recommendations are based);

“(iv) taking into account the comments and recommendations (and accompanying data) received at such meeting, develops and makes available to the public (through an Internet site and other appropriate mechanisms) a list of proposed determinations with respect to the appropriate basis for establishing a payment amount under this subsection for each such code, together with an explanation of the reasons for each such determination, the data on which the determinations are based, and a request for public written comments on the proposed determination; and

“(v) taking into account the comments received during the public comment period, develops and makes available to the public (through an Internet site and other appropriate mechanisms) a list of final determinations of the payment amounts for such tests under this subsection, together with the rationale for each such determination, the data on which the determinations are based, and responses to comments and suggestions received from the public.

“(C) Under the procedures established pursuant to subparagraph (A), the Secretary shall—

“(i) set forth the criteria for making determinations under subparagraph (A); and

“(ii) make available to the public the data (other than proprietary data) considered in making such determinations.

“(D) The Secretary may convene such further public meetings to receive public comments on payment amounts for new tests under this subsection as the Secretary deems appropriate.

“(E) For purposes of this paragraph:

“(i) The term ‘HCPCS’ refers to the Health Care Procedure Coding System.

“(ii) A code shall be considered to be ‘substantially revised’ if there is a substantive change to the definition of the test or procedure to which the code applies (such as a new analyte or a new methodology for measuring an existing analyte-specific test).”.

SEC. 702. ONE YEAR DELAY IN LOCK IN PROCEDURES FOR MEDICARE+CHOICE PLANS.

Section 1851(e) (42 U.S.C. 1395w-21(e)) is amended—

(1) in paragraph (2)(A), by striking “THROUGH 2001” and “and 2001” and inserting “THROUGH 2002” and “2001, and 2002”, respectively;

(2) in paragraph (2)(B), by striking “DURING 2002” and inserting “DURING 2003”;

(3) in paragraphs (2)(B)(i) and (2)(C)(i), by striking “2002” and inserting “2003” each place it appears;

(4) in paragraph (2)(D), by striking “2001” and inserting “2002”; and

(5) in paragraph (4), by striking “2002” and inserting “2003” each place it appears.

PURPOSE AND SUMMARY

The purpose of H.R. 3046, the Medicare Regulatory, Appeals, Contracting, and Education Reform Act, is to streamline Medicare’s regulatory process, ease paperwork burdens, and improve Medicare’s responsiveness to beneficiaries and health care providers. Most importantly, this legislation addresses the need for consistent and accurate written responses from Medicare contractors. It also includes significant reform of Medicare’s contracting and administrative appeals processes, and improvements in beneficiary and provider outreach and education.

BACKGROUND AND NEED FOR LEGISLATION

Covering about 40 million beneficiaries at an annual cost of nearly \$240 billion, the Medicare program is the nation’s largest health insurance program. It enrolls and pays claims from nearly one million providers of services, physicians, practitioners, facilities, suppliers, and health plans. The Centers for Medicare and Medicaid Services (CMS) is the federal agency that administers Medicare, relying on contractors to annually process and pay about 900 million claims for services furnished under the traditional fee-for-service program.

The complexity of the Medicare program and the environment in which CMS operates is widely recognized. Because of the large number of laws and regulations that govern the Medicare program, many health care providers are forced to spend as much time negotiating the maze of CMS bureaucracy as they do treating patients. Complaints about confusing and burdensome regulations are common.

Over the past year, the Subcommittee on Health and the Subcommittee on Oversight and Investigations conducted a comprehensive review of the major programs, policies, and operations of CMS, focusing specifically on the agency's administration of the Medicare program. As part of this ongoing initiative, known as "Patients First: A 21st Century Promise to Ensure Quality and Affordable Health Coverage," the Subcommittees examined the current complexities in the Medicare program, the extent to which such complexities are affecting patient care, and the role Congress can play in addressing these concerns.

In an effort to identify concerns and burdens that Medicare beneficiaries and health care providers face on a daily basis, the Committee on Energy and Commerce disseminated two surveys, one for beneficiaries and the other for health care providers. These surveys were designed to elicit input about ways the delivery of quality health care could be improved and waste, mismanagement, and bureaucratic delays could be eliminated. The surveys asked Medicare's true stakeholders—beneficiaries and health care providers—to report on their interactions with the Medicare program and identify areas where problems exist. The provider survey also asked providers of services, physicians, practitioners, facilities, and suppliers to identify some of the most burdensome regulations they deal with routinely, as well as provide recommendations to improve the federal health care system. With more than 3,500 responses, the surveys were a valuable Committee resource.

Through the "Patients First" project and survey responses, the Committee documented and identified many of the complexities of the Medicare program and the systemic problems faced by Medicare beneficiaries and health care providers. For example, the majority of health care providers who responded to the Committee's survey described the difficulty associated with getting guidance from CMS to appropriately navigate the federal rules and regulations governing Medicare, often describing the inconsistent information they receive when seeking answers to their questions. In addition, many health care providers stated that the educational materials they receive from Medicare are neither clear nor concise. Further, many beneficiaries reported problems with Medicare's customer service.

Representatives Toomey and Berkley introduced legislation earlier this year to address many of these problems. Their legislation focused specifically on the concern that Medicare's complexity and extensive paperwork requirements were detracting from the time physicians could spend with patients as well as the time they could spend learning about new medical advancements. The Medicare Regulatory, Appeals, Contracting, and Education Reform Act builds upon this earlier legislation. The Committee worked with stakeholders, including provider associations, beneficiary groups, and government officials, to balance the government's obligation to pro-

tect the Medicare Trust Funds with the need to reform Medicare for the provider community and the patients it serves. The Medicare Regulatory, Appeals, Contracting, and Education Reform Act embodies this balance.

HEARINGS

The Subcommittee on Health held four joint hearings with the Subcommittee on Oversight and Investigations as part of the “Patients First” initiative.

The first hearing, held on Thursday, March 1, 2001, examined Medicare’s processes for determining coverage, assigning billing codes, and setting payment levels. The Subcommittees received testimony from: Mr. Art Linkletter, National Spokesman, United Seniors Association; Dr. Paul Shreve, Director, General Nuclear Imaging Section, University of Michigan Medical Center; Ms. Kathy Dziuba, Rochester Hills, Michigan; Dr. Jeffrey J. Popma, Director, Interventional Cardiology, Brigham and Women’s Hospital; Mr. Donald Latulippe, Boston, Massachusetts; Dr. Jeffrey Kang, Director, Office of Clinical Standards and Quality, Health Care Financing Administration (now the Centers for Medicare and Medicaid Services); Dr. Clifford Goodman, Senior Scientist for Medical Technology, Lewin Group; and Dr. Murray N. Ross, Executive Director, Medicare Payment Advisory Commission.

The second hearing, held on Wednesday, April 4, 2001, focused on how the Health Care Financing Administration (now the Centers for Medicare and Medicaid Services) interacts with health care providers regarding the rules and regulations that guide the Medicare program. The Subcommittees received testimony from: Dr. Mark Miller, Acting Director, Center for Health Plans and Providers, Health Care Financing Administration (now the Centers for Medicare and Medicaid Services); Mr. Michael Mangano, Acting Inspector General, Department of Health and Human Services; Dr. David Becker, Largo, Florida, on behalf of the Pinellas County Medical Society; Jyl D. Bradley, Administrator, Dunning Street Ambulatory Care Center, on behalf of the Medical Group Management Association; Dr. Douglas L. Wood, Vice Chair, Department of Medicine, Mayo Foundation; and Mr. Harvey Friedman, Vice President, Medicare and Seniors Program, Blue Cross Blue Shield Association.

The third hearing, held on Thursday, May 10, 2001, featured four former administrators of the Health Care Financing Administration (now the Centers for Medicare and Medicaid Services) to discuss what works at the agency and what can be improved. The Subcommittees received testimony from: Mr. William L. Roper, Dean of the School of Public Health, University of North Carolina at Chapel Hill; Dr. Gail R. Wilensky, John M. Olin Senior Fellow, Project HOPE, and Chair of the Medicare Payment Advisory Commission; Dr. Bruce C. Vladeck, Senior Vice President for Policy, Institute for Medicare Practice, Mount Sinai School of Medicine; and Ms. Nancy-Ann Min DeParle, the immediate former administrator of the Health Care Financing Administration (now the Centers for Medicare and Medicaid Services).

The fourth hearing, held on Thursday, June 28, 2001, examined Medicare’s existing contracting authority and proposals to refine this authority to secure the efficient and responsive delivery of high

quality services to Medicare beneficiaries. The Subcommittees received testimony from: Mr. Thomas Scully, Administrator, Centers for Medicare and Medicaid Services; Mr. Michael Mangano, Acting Inspector General, Department of Health and Human Services; Ms. Leslie G. Aronovitz, Director, Health Care-Program Administration and Integrity Issues, U.S. General Accounting Office; Mr. Scott P. Serota, President and Chief Executive Officer, Blue Cross Blue Shield Association; Mr. Timothy F. Cullen, Chairman of the Board, United Government Services, LLC; and Mr. Alfred J. Chiplin, Jr., Managing Attorney, Health Care Rights Project, Center for Medicare Advocacy.

COMMITTEE CONSIDERATION

On Wednesday, October 17, 2001, the Subcommittee on Health met in open markup session and approved H.R. 3046, the Medicare Regulatory, Appeals, Contracting, and Education Reform Act, for Full Committee consideration, as amended, by a voice vote. On Wednesday, October 31, 2001, the Committee on Energy and Commerce met in open markup session and favorably ordered reported H.R. 3046, as amended, by a voice vote.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. There were no record votes taken in connection with ordering H.R. 3046 reported. A motion by Mr. Tauzin to order H.R. 3046 reported to the House, as amended, was agreed to by a voice vote.

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee held four oversight hearings and made findings that are reflected in this report.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The objective of H.R. 3046 is to provide regulatory relief to providers of services, physicians, practitioners, facilities, and suppliers furnishing health care services to Medicare beneficiaries and improve education and outreach to beneficiaries and providers.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 3046, the Medicare Regulatory, Appeals, Contracting, and Education Reform Act, would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, December 4, 2001.

Hon. W.J. "BILLY" TAUZIN,
*Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 3046, the Medicare Regulatory and Contracting Reform Act of 2001.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contacts are Alexis Ahlstrom and Niall Brennan.

Sincerely,

STEVEN LIEBERMAN
(For Dan L. Crippen, Director).

Enclosure.

H.R. 3046—Medicare Regulatory and Contracting Reform Act of 2001

Summary: The Medicare Regulatory and Contracting Reform Act of 2001 would require the Centers for Medicare and Medicaid Services (CMS) to modify how Medicare regulations and policies are developed, communicated, and enforced, and would modify the procedures used to resolve disputes involving payment for services covered by Medicare. The bill would transfer certain administrative law judges from the Social Security Administration (SSA) to the Department of Health and Human Services (HHS). It would change the procedures by which Medicare makes contracts with entities to process and pay claims, and it would place new requirements on those contractors. It would require the Secretary of HHS to conduct several demonstrations, and would require the completion of several studies and reports.

The bill would also affect direct spending by changing procedures for determining whether a service is covered by Medicare, and by appropriating additional funds to the Medicare Integrity Program.

CBO estimates that implementing H.R. 3046 would cost \$59 million in 2002 and \$1.4 billion over the 2002–2006 period from appropriated funds. CBO also estimates that implementing the bill would increase direct spending by \$27 million in 2002, \$1.3 billion over the 2002–2006 period, and \$5.4 billion over the 2002–2011 period. Because the bill would affect direct spending, pay-as-you-go procedures would apply.

H.R. 3046 would preempt state and local laws governing liability for Medicare administrative contractors in some cases. This preemption would be an intergovernmental mandate as defined in the Unfunded Mandates Reform Act (UMRA) because it would prevent the application of state laws. However, because the preemption would not require state or local governments to make any specific

action, it would impose no costs on those governments. Other provisions of the bill would have no significant effect on the budgets of state, local, or tribal governments. H.R. 3046 contains no private-sector mandates as defined in UMRA.

Estimated cost to the Federal Government: Table 1 shows the estimated authorization levels and outlays for Medicare administrative expenses under current law and under H.R. 3046. Assuming appropriation of the estimated amounts, CBO estimates that implementing H.R. 3046 would cost \$59 million in 2002 and \$1.4 billion over the 2002–2006 period. The table also shows the estimated effect of H.R. 3046 on direct spending, a total of \$1.3 billion over the 2002–2006 period. The costs of this legislation fall within budget function 570 (Medicare).

TABLE 1.—ESTIMATED BUDGETARY IMPACT OF H.R. 3046

| | By fiscal year, in millions of dollars— | | | | | |
|---|---|---------|---------|---------|---------|---------|
| | 2001 | 2002 | 2003 | 2004 | 2005 | 2006 |
| SPENDING SUBJECT TO APPROPRIATION | | | | | | |
| Spending for Medicare Administrative Costs Under Current Law: | | | | | | |
| Estimated Budget Authority ¹ | 3,352 | 3,500 | 3,646 | 3,797 | 3,955 | 4,118 |
| Estimated Outlays | 3,321 | 3,464 | 3,631 | 3,757 | 3,913 | 4,074 |
| Proposed Changes: | | | | | | |
| Estimated Authorization Level | 0 | 65 | 416 | 347 | 264 | 318 |
| Estimated Outlays | 0 | 59 | 381 | 354 | 273 | 312 |
| Spending for Medicare Administrative Costs Under H.R. 3046: | | | | | | |
| Estimated Authorization Level ¹ | 3,352 | 3,565 | 4,062 | 4,144 | 4,219 | 4,436 |
| Estimated Outlays | 3,321 | 3,523 | 4,012 | 4,111 | 4,186 | 4,386 |
| DIRECT SPENDING | | | | | | |
| Medicare Spending Under Current Law ² : | | | | | | |
| Estimated Budget Authority | 214,473 | 225,915 | 240,076 | 255,769 | 278,493 | 294,073 |
| Estimated Outlays | 214,114 | 225,933 | 239,855 | 256,065 | 278,411 | 293,843 |
| Proposed Changes: | | | | | | |
| Estimated Budget Authority | 0 | 27 | 131 | 243 | 385 | 554 |
| Estimated Outlays | 0 | 27 | 122 | 243 | 385 | 554 |
| Medicare Spending Under H.R. 3046 ² : | | | | | | |
| Estimated Budget Authority | 214,473 | 225,942 | 240,207 | 256,012 | 278,878 | 294,627 |
| Estimated Outlays | 214,114 | 225,960 | 239,977 | 256,308 | 278,796 | 294,397 |

¹ Budget authority and outlays for 2001 are the amounts appropriated and spent that year.

² Includes direct spending for benefits and administrative costs less premium receipts.

Basis of estimate: For this estimate, CBO assumes that the legislation would be enacted this fall and that estimated amounts would be appropriated each year.

Spending subject to appropriations

Contracting Reform.—Under current law, CMS contracts with fiscal intermediaries and carriers to process and pay claims, to educate providers regarding Medicare billing policy, and for other purposes. This bill would change the activities required of contractors and the methods by which CMS enters into contracts and oversees the activities of contractors. CBO estimates that these provisions would increase the cost of administering contracts and the total amount CMS spends on contracts by \$35 million in 2002 and \$1.2 billion over the 2002–2006 period.

Contracting Changes. H.R. 3046 would direct CMS to provide incentives to contractors who meet or exceed certain performance

standards. Based on information furnished by CMS, we estimate that the incentive payments would total 3 percent of operating payments to contractors, or about \$233 million over the 2002–2006 period.

H.R. 3046 would require CMS to competitively bid contracts with fiscal intermediaries and carriers at least every five years. CBO expects that an additional 3–5 full-time-equivalent employees (FTEs) at the GS–12 level would be needed throughout the period to write new competitively-bid contracts. The estimate assumes that about one-quarter of the contracts would be awarded to a nonincumbent bidder, and that it would cost about \$2 million to transition between contractors. CBO estimates that implementing this provision would cost about \$54 million over the 2002–2006 period.

Contractor Oversight. In addition, the bill would direct Medicare program to measure the payment error rates for individual contractors, which are believed to indicate how well providers understand proper Medicare billing procedures, with the intent of identifying contractors who have achieved high levels of provider education. This provision would expand current practice, which is to calculate system-wide error rates. The bill would also expand the requirement for contractors to monitor the accuracy of information given to providers and the timeliness of contractors' processing of providers' enrollment applications. CBO estimates that complying with these provisions would cost about \$30 million over the 2002–2006 period.

New Contractor Activities. The bill would require contractors to respond to written requests for guidance within 45 days of receipt, and would make that response binding on the Medicare program. We expect that contractors would receive 50 percent more written requests under H.R. 3046 than they would under current law, with each request costing \$15 dollars to process in 2002. This, plus the requirement that contractors respond to those requests within 45 days, would require contractors to hire additional employees. CBO estimates that implementing these provisions would cost \$11 million in 2002 and \$76 million over the 2002–2006 period.

Beginning in July 2003, the bill would require contractors, upon request of a beneficiary or provider, to make a determination about whether Medicare will cover a particular service or item before that service is furnished. The contractor would be required to conduct a medical review and to make the coverage decision within 45 days. CBO estimates that contractors would make about 100,000 determinations a year at an average cost of about \$100 per determination (at 2003 prices). We estimate the cost of administering this program would total \$35 million over the 2002–2006 period.

The bill would require contractors to create a system by which providers may resubmit claims originally submitted with errors or omissions without having to pursue payments via the appeals process. CBO estimates the cost of developing and operating systems to process these resubmitted claims would total \$5 million in 2002 and \$46 million over the 2002–2006 period.

The bill would require contractors to give providers or beneficiaries, upon request, a summary of the clinical and scientific evidence used in making a determination. CBO estimates the cost of making available scientific and clinical evidence on determinations would total \$686 million over the 2002–2006 period.

Appeals Reform.—H.R. 3046 would change the processes by which Medicare adjudicates appeals by providers of payment denials and conducts compliance actions against providers. The bill would delay the date by which CMS is required to implement certain provisions of the Beneficiary Improvement and Protection Act and modify other provisions. It would also create a new mechanism for individuals to challenge National Coverage Determinations (NCDs.) CBO estimates that implementing these provisions would cost \$8 million in 2002 and \$114 million over the 2002–2006 period.

Administrative Law Judge Transfer. The bill would transfer certain administrative law judges (ALJs) from the Social Security Administration to the Department of Health and Human Services and would permit the Secretary to hire more ALJs. CBO estimates that the costs of planning and implementing the transfer, adding ALJs, and providing the ALJs with additional training on Medicare issues would be \$1 million in 2002 and would total \$39 million over the 2002–2006 period.

Standardization of Compliance and Appeals Actions. The bill would also standardize existing policies regarding the use of random and non-random prepayment review, the use of extrapolation in the case of overpayments, and the offering of repayment plans in the case of overpayment. In addition, H.R. 3046 would create procedures by which appellants may petition for expedited access to judicial review in federal district court in certain circumstances. CBO estimates that implementing those provisions would cost \$34 million over the 2002–2006 period. These provisions would require CMS to make changes to current appeals and compliance systems but would not change the conditions under which Medicare would make payments to providers. Therefore, CBO estimates that these provisions would have no effect on direct spending.

National Coverage Determinations. H.R. 3046 would also establish a process for seeking exceptions to national coverage determinations under special medical circumstances. In general, new medical technologies are integrated into existing Medicare payment systems as soon as they are approved by the Food and Drug Administration. However, in certain instances, breakthrough technologies that are clinically different from existing treatment options require a more detailed examination, either at the local level by Medicare contractors, or through an NCD issued by CMS.

Current law provides for a process by which Medicare-eligible individuals seeking coverage of a service excluded by an NCD can appeal that decision. Such an appeal would be reviewed by the Departmental Appeals Board (DAB) of the Department of Health and Human Services. If the DAB determines that there is inadequate information to support the validity of an NCD, it can permit the taking of evidence to evaluate the reasonableness of the NCD. However, CMS has not yet established a formal appeals process for NCDs, and no appeals have been filed to date.

In addition to the current NCD appeals process, H.R. 3046 would require the Secretary to establish a process whereby Medicare-eligible individuals may request an exception, due to their special medical circumstances, to an NCD that has the effect of denying coverage for items and services for the treatment of a serious or life-threatening condition. Furthermore, these special medical cir-

cumstances must not have been considered during the initial NCD process. Each request would be reviewed by an independent panel of physicians or other health care professionals. If the panel supports the request for an exception, the NCD would not be applied by any Medicare contractor with respect to treatment for that individual.

CBO assumes that the two appeals process are not perfect substitutes. Specifically, CBO assumes that some individuals who would not appeal an NCD under current law would request an exception to an NCD under the procedures outlined in H.R. 3046. CBO estimates that this provision would result in an additional 3,000 requests for exceptions above and beyond the existing NCD appeals process beginning in 2003. CBO estimates that adjudicating these requests for exceptions, including assembling panels of physicians, would cost \$6 million over the 2002–2006 period. (The additional claims payments that would result from this process would be direct spending and are discussed later in this estimate.)

Demonstrations and New program Areas.—H.R. 3046 would direct CMS to expand its programs to educate beneficiaries and providers. CBO estimates that implementing these provisions would cost \$6 million in 2002 and \$35 million during the 2002–2006 period.

The bill would direct CMS to implement a three-year outreach demonstration in at least six locations throughout the United States. The program would involve the deployment of Medicare specialists to local Social Security Administration offices to provide beneficiaries assistance and advice regarding the Medicare program. CBO estimates that the costs of the demonstration, which would include the rental of office space, salaries for Medicare specialists, and travel, moving, and administrative expenses, would total \$4 million over the 2002–2006 period.

H.R. 3046 would require CMS to designate a person to act as a liaison between providers and Medicare and to respond to providers' complaints. CBO assumes that in order to comply with this provision, this person would require the aid of several staff members. CBO estimates the cost of implementing this provision would be \$4 million in 2002 and \$31 million over the 2002–2006 period.

Development of Policies, Procedures, and Time Lines.—H.R. 3046 would require CMS to develop new policies, procedures, and time lines with regard to the issuance of regulations and documentation guidelines for evaluation and management services. CBO estimates the cost of implementing these provisions would be \$10 million in 2002 and \$38 million during the 2002–2006 period.

Final Regulations. The bill would require CMS to create a time line for publishing final regulations and would limit publication of new regulations to once a month. There currently are 22 “interim final rules”; the bill would require CMS to make those rules final, and would require CMS to finalize all future regulations. We estimate that CMS would need to hire an additional 3 to 5 people, at the GS–11 level or higher, to comply with the requirement to finalize all future interim regulations and to produce the required reports. CBO estimates the cost of implementing these provisions would be \$9 million in 2002 and \$19 million during the 2002–2006 period.

Documentation Guidelines for Evaluation and Management (E&M) Services. H.R. 3046 would restrict CMS from implementing new documentation guidelines for evaluation and management services until several conditions have been met. Those conditions include:

- Establishing plans to improve the guidelines;
- Completing pilot projects to test modifications to the guidelines;
- Educating providers about the guidelines; and
- Consulting providers during the entire process of testing and establishing the guidelines.

CMS currently has E&M guidelines in place, and the bill would not require changes in those guidelines. CBO assumes that CMS will attempt to update those guidelines during the next few years, because both CMS and provider groups have expressed interest in doing so. The new procedural requirements would increase the cost of developing and implementing new E&M guidelines. Establishing new guidelines for E&M documentation would require the hiring of at least two FTEs for the administration of the pilot projects, for outreach to providers, and for consultation with providers. CBO further estimates that CMS would conduct at least three pilot projects, with each project costing around \$1 million per year, and that the studies and reports required by these provisions would cost another \$1 million.

Direct spending

H.R. 3046 would change the conditions under which Medicare would pay for services, create a process to establish whether an item or service is covered prior to a beneficiary receiving the service, and create mechanisms by which previously excluded services would be provided in special medical circumstances. The bill would also appropriate funds to the Medicare Integrity Program.¹ CBO estimates that implementing H.R. 3046 would increase direct spending by \$27 million in 2002, \$1.3 billion over the 2002–2006 period, and \$5.4 billion over the 2002–2011 period.

In general, if a provider is not certain whether Medicare will pay for a service or item in a particular case, there is no process under current law that enables the provider or beneficiary to find out in advance whether Medicare will pay for that service or item. In such cases, the provider may request that the beneficiary sign an advanced beneficiary notice (ABN) by which the beneficiary accepts responsibility for paying for the service if Medicare denies payment. (The provider is prohibited from charging the beneficiary if the beneficiary does not sign an ABN and Medicare subsequently denies payment.)

The bill would authorize the Secretary to specify services for which the provider or beneficiary may request a coverage determination before a service is furnished. Upon receipt of such a request, the bill would require the contractor to conduct a medical review and issue a decision within 45 days.

CBO estimates that contractors would process about 100,000 requests for prior determination each year, and that half of those requests would be approved. CBO assumes that:

¹ Funds appropriated by an authorizing bill are considered direct spending.

- About three-quarters of the approved requests would involve beneficiaries who, under current law, would choose the lower-priced service when offered the choice of a lower-priced service that Medicare is known to cover and a higher-priced service involving an ABN; in such cases, the new process would result in the use of higher-priced services.

- About one-quarter of the approved requests would involve beneficiaries who, under current law, would decline a relatively high-cost service when asked to sign an ABN; in such cases, the new process would result in the use of additional services.

- Very few requests would involve beneficiaries who, under current law, would sign an ABN and receive a service for which Medicare coverage is uncertain.²

For beneficiaries who would receive a lower-priced service under current law, the estimate assumes there would be a difference of about \$250, on average, between the services furnished under current law and services furnished following approval for Medicare payment; the average added cost for beneficiaries who would decline a service under current law would be \$500, we estimate. Those amounts are in 2003 prices, and include the cost of additional visits for beneficiaries who return to a provider after receiving approval for Medicare payment. CBO estimates that the cost of complying with this provision would be \$187 million over the 2002–2011 period.

Under current law, relatives of beneficiaries cannot receive payments from Medicare for the provision of items or services to that beneficiary. H.R. 3046 would eliminate that restriction for relatives who provide care to beneficiaries in rural areas. CBO expects that this provision would have a particularly strong impact in the area of home health care—increasing spending on home health care by an estimated 2 percent—because some care givers would become employed by home health agencies to get paid for the care that they currently provide without remuneration. CBO estimates the cost of implementing this provision would be \$27 million in 2002 and \$4.6 billion over the 2002–2011 period.

The bill would allow beneficiaries to appeal national coverage determinations based on their individual medical circumstances. CBO estimates that this provision would result in an additional 3,000 requests for exceptions above and beyond the existing NCD appeals process, beginning in 2003. We estimate that the cost of paying claims related to these exceptions would not increase direct spending in 2002, but would increase direct spending by \$376 million over the 2002–2011 period.

H.R. 3046 would appropriate \$35 million a year in additional funds to the Medicare Integrity Program beginning in fiscal year 2003. CBO estimates this provision would increase direct spending by \$306 million over the 2002–2011 period.

Under current law, if a beneficiary dies after receiving services from a provider who does not accept assignment (that is, for all services furnished to Medicare beneficiaries, agree to accept payment at Medicare rates as payment in full), the provider may not appeal a denial of payment. The bill would permit those providers

²The vast majority of ABNs are for low-cost items and services (the average payment for approved services is about \$18). CBO believes that beneficiaries are unlikely to request prior determination and wait up to 45 days for an answer for such low-cost services.

to make such appeals. CBO estimates that enacting this provision would result in about 2,000 denials being reversed and paid each year. We estimate that this provision would not have a significant effect on spending in 2002, and would increase spending by \$5 million over the 2002–2011 period.

Pay-as-you-go considerations: The Balanced Budget and Emergency Deficit Control Act sets up pay-as-you-go procedures for legislation affecting direct spending or receipts. The table below shows the effect of H.R. 3046 on direct spending. For pay-as-you-go purposes, only the effects in the current year, the budget year, and the succeeding four years are counted.

| | By fiscal year, in millions of dollars— | | | | | | | | | | |
|---------------------------|---|------|------|------|------|------|------|------|------|-------|--|
| | 2002 | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | |
| Changes in outlays | 27 | 122 | 243 | 385 | 554 | 629 | 713 | 807 | 912 | 1,044 | |
| Changes in receipts | Not applicable | | | | | | | | | | |

Estimated impact on state, local, and tribal governments: H.R. 3046 would preempt state and local laws governing liability for Medicare administrative contractors in some cases. This preemption would be an intergovernmental mandate as defined in UMRA because it would prevent the application of state laws. However, because the preemption would not require the state or local governments to take any specific action, it would impose no costs on those governments. Other provisions of the bill would have no significant effect on the budgets of state, local, or tribal governments.

Estimated impact on the private sector: H.R. 3046 contains no private-sector mandates as defined in UMRA.

Estimate prepared by: Federal Costs: Alexis Ahlstrom and Niall Brennan. Impact on State, Local, and Tribal Governments: Leo Lex. Impact on the Private Sector: Stuart Guterman.

Estimate approved by: Robert A. Sunshine, Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the Committee finds that the Constitutional authority for this legislation is provided in Article I, section 8, clause 3, which grants Congress the power to regulate commerce with foreign nations, among the several States, and with the Indian tribes.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or

accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title; amendments to Social Security Act; table of contents

Section 1 provides the short title of the legislation, the Medicare Regulatory, Appeals, Contracting, and Education Reform Act. Except as otherwise specified, the provisions of this bill would amend or repeal a section or other provisions of the Social Security Act. “BIPA” means the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 and “Secretary” means the Secretary of the Department of Health and Human Services (HHS).

Section 2. Findings

In this section, Congress finds that the overwhelming majority of providers of services, physicians, practitioners, facilities, and suppliers are law-abiding citizens providing important services and care to Medicare beneficiaries each day and directs the Secretary to streamline Medicare’s paperwork requirements and clarify its instructions so that time spent on patient care can increase.

Section 3. Construction

Section three states that none of the provisions shall be construed to (1) compromise the existing legal authority for addressing Medicare fraud or abuse with respect to criminal prosecution, civil enforcement, or administrative remedies, including those established by the False Claims Act or (2) prevent the Department of Health and Human Services (HHS) from its ongoing efforts to eliminate waste, fraud, and abuse in Medicare. Also, consolidation of Medicare’s administrative contracting (as provided for in this bill) would not consolidate the Federal Hospital Insurance Trust Fund, which pays for part A services and the Federal Supplementary Medical Insurance Trust Fund, which pays for part B services. The bill notes that this administrative consolidation does not reflect any position on that issue.

TITLE I—REGULATORY REFORM

Section 101. Issuance of regulations

Under current law, the Secretary is required to prescribe regulations that are necessary to administer parts A and B of the Medicare program. No rule, requirement, or policy statement (other than a national coverage determination) that establishes or changes a substantive legal standard determining Medicare’s scope of benefits, level of payment, or eligibility of individuals, entities, or organizations to receive benefits or furnish services can take effect unless it is promulgated by regulation. The Secretary must publish a proposed regulation in the Federal Register, with at least 60 days to solicit public comment, before issuing the final regulation with the following exceptions: (1) the statute permits the regulation to be issued in interim final form or provides for a shorter public comment period; (2) the statutory deadline for implementation of a provision is less than 150 days after the date of enactment of the statute containing the provision; (3) under the good cause ex-

ception contained in the rule-making provision of Title 5 of the United States Code, notice and public comment procedures are deemed impracticable, unnecessary, or contrary to the public interest. The Secretary must publish in the Federal Register no less frequently than every three months a list of all manual instructions, interpretative rules, statements of policy, and guidelines, which are promulgated to carry out Medicare law.

This section requires the Secretary to issue final and interim final regulations on one business day of every month, unless the Secretary finds that publication on other dates is required to comply with Medicare law or that this restriction is contrary to the public interest. In such instances, the Secretary would be required to include an explanation of such a finding when the regulations are issued. The Comptroller General of the U.S. General Accounting Office (GAO) would be required to report to Congress within three years on the feasibility of issuing regulations on one day each calendar quarter.

The Secretary, in consultation with the Office of Management and Budget, would establish a regular timeline for the publication of final regulations based on the previous publication of a proposed regulation or interim final regulation. Timelines may vary for different regulations based on differences in the regulatory complexity and the scope and number of comments received. However, the Secretary would be required to publish a final regulation within the 12-month period following the publication of an interim final regulation. The final regulation would include responses to comments submitted in response to the interim final regulation. If the final regulation is not published by that 12-month deadline, the interim final regulation would not remain in effect unless the Secretary publishes a notice before the deadline that establishes a good cause for the delay and extends the deadline.

Provisions that are not logical outgrowths of proposed regulations would be effective only after a public comment period and separate publication as a final regulation. The logical outgrowth provision would not apply to interim final regulations. The Committee on Energy and Commerce recognizes that proposed regulations for annual payment updates for providers and suppliers include proposed overall payment updates, and that specific payment amounts for specific codes or specific payment areas are not typically included until final rules. The Committee does not intend to change past custom to recognize such details in final rules as a "logical outgrowth" of proposed rules.

The publication restriction applies to regulations promulgated on or after 30 days from the date of enactment. The regular timeline requirement is effective on enactment. The Secretary shall provide for an appropriate transition for the backlog of previously published interim regulations. The logical outgrowth provision applies to final regulations published on or after enactment.

Section 102. Compliance with changes in regulations and policies

In section 102, a substantive change in a regulatory or a sub-regulatory issuance would not be applied retroactively to items or services, unless the Secretary determines that retroactive application (1) would be necessary to comply with statutory requirements or (2) would be beneficial to the public interest.

After enactment, a compliance action against a provider of services, physician, practitioner, facility, or supplier with respect to such a substantive change would be permitted for items and services furnished on or after the effective date of the change. The substantive change would be effective not earlier than 30 days after its issuance or publication date except when the Secretary waives the 30-day period to comply with statutory requirements or finds such a waiver to be in the public interest. The Secretary would be required to include a brief explanation of such a finding in the issuance or publication of the substantive change if an earlier date is established.

The effective date for substantive changes and compliance actions is on or after enactment.

Section 103. Report on regulatory burdens

This section requires the Secretary to report to Congress on the administration of the Medicare program and inconsistencies among existing Medicare statutory or regulatory provisions. The report would include (1) information from beneficiaries, providers of services, practitioners, facilities, suppliers, provider facilitators (established in Section 404 of this legislation), and Medicare contractors; (2) descriptions of efforts to reduce inconsistencies; and (3) recommendations from the Secretary for appropriate legislation or administrative actions. The report would be due no later than two years after enactment and every two years thereafter.

This section is effective upon enactment.

Section 104. GAO report on the sustainable growth rate and regulatory costs

This section would require the GAO to report to Congress on the accuracy of the sustainable growth rate (SGR) in accounting for regulatory costs imposed on physicians for 2002 and subsequent years. The report is due no later than 18 months after enactment.

Section 105. GAO report on requirement for submission of claims for categorically excluded dental services

This section would require the GAO to submit a report to Congress on the extent to which group health plans or other insurers require dentists to obtain documentation from Medicare that categorically excluded dental services are not covered prior to paying the claim. The report would include the number of Medicare beneficiaries that request dentists to submit claims to Medicare for these excluded dental services. The report is due no later than 18 months after enactment.

TITLE II—APPEALS PROCESS REFORM

Section 201. Transfer of responsibility for Medicare appeals

Under current law, Medicare beneficiaries and, in certain circumstances, providers and suppliers of health care services may appeal claims that are denied or payments that are reduced. Section 1869 of the Social Security Act, which governs Medicare claims appeals, was amended by BIPA in its entirety. However, the BIPA provisions are not yet effective. Generally, parties who have been denied coverage of an item or service have the right to appeal that

decision administratively and then may go to federal district court. A hearing by an administrative law judge (ALJ) in the Social Security Administration (SSA) and review by the Departmental Appeals Board (DAB) are components of the administrative appeals process.

This section requires the Commissioner of SSA and the Secretary to develop a plan by October 1, 2002 to transfer the functions of the administrative law judges (ALJs) who are responsible for hearing Medicare and Medicare-related cases from SSA to HHS. The plan would be transmitted to Congress and the GAO no later than October 1, 2002, and would include (1) information on the number of ALJs and support staff required now and in the future to hear and decide cases in a timely manner, taking into account the current and anticipated number of claims, appeals, beneficiaries, and statutory changes; (2) cost projections for FY2004 and subsequently; (3) a timetable for the transition; (4) information on regulations needed to govern the appeals process; (5) the development of a case tracking system that would accommodate the maintenance and transfer of case specific data across the fee-for-service and managed care components of Medicare; (6) the feasibility of giving binding, precedential authority to DAB decisions that address broad legal issues; and (7) the feasibility of filing appeals electronically or through video conferencing. This plan would also include recommendations for further Congressional action, including modifications to the appeals requirements and deadlines imposed by BIPA. The GAO would evaluate the plan and submit a report to Congress by April 1, 2003.

The Secretary and the Commissioner of SSA would implement the transition plan and transfer the ALJ functions no earlier than July 1, 2003 but no later than October 1, 2003. The Secretary would (1) assure the ALJ's independence from CMS; and (2) locate the ALJs with an appropriate geographic distribution to ensure continued access.

Subject to appropriations, the Secretary would be permitted to hire ALJs and support staff with priority given to ALJs with experience in handling Medicare appeals. Amounts previously paid to SSA for the ALJs performing the Medicare ALJ functions would be paid to the Secretary. The Secretary would be permitted to enter into arrangements with SSA to share office space, support staff, and other resources with appropriate reimbursement from the Medicare Trust Funds. Increased appropriations would be permitted to ensure timely action on appeals before ALJs and the DAB. Additional appropriations would be used to increase the number of ALJs and support staff, improve education and training for ALJs and their staff, and increase DAB staff.

This section is effective upon enactment unless otherwise specified.

Section 202. Expedited access to judicial review

Section 521 of BIPA (which is not yet implemented) amends Section 1869 to establish deadlines for filing appeals and for making decisions in the Medicare appeals process. Generally, an initial determination is to be completed no later than 45 days from the date a claim for benefits is received. An individual dissatisfied with an initial determination is entitled to a redetermination by a carrier or fiscal intermediary if requested within 120 days of the deter-

mination date. The redetermination is to be completed no later than 30 days from the request date. The Secretary may reopen or revise any initial determination or reconsidered determination under guidelines established by regulation.

An individual dissatisfied with the redetermination is entitled to a reconsideration by a qualified independent contractor (QIC) if the request is initiated within 180 days of the notice of the adverse redetermination. With certain exceptions, a QIC reconsideration decision is to be completed within 30 days from the date a timely request has been filed. After a QIC's reconsideration, if the contested amount is greater than \$100, an individual is entitled to a hearing before an ALJ and then a review by the DAB. Both the ALJ hearing and the DAB review are to be completed within 90 days of a timely filed request for such an action.

If the dispute is not satisfactorily resolved and the contested amounts are greater than \$1,000, the individual is entitled to judicial review of the decision. Under certain circumstances, a beneficiary is entitled to an expedited determination with accelerated deadlines. BIPA also provides for an expedited hearing in cases where the moving party alleges that no material issues of fact are in dispute. The Secretary makes an expedited determination as to whether any such facts are in dispute and, if not, renders a decision expeditiously.

This section would require the Secretary to establish an appeals process that would permit access to judicial review when a review panel determines, no later than 60 days after the date of the written request and submission of supporting documentation, that no entity within the administrative appeals process has the authority to decide the question of law or regulation relevant to the matter in controversy and there are no material facts in dispute. A review panel would consist of a panel of three members from the DAB. An appellant would go straight to the DAB in these cases; no additional steps in the administrative appeals process would be necessary. The appellant would be able to make such request only once with respect to a question of law or regulation for a specific dispute. The determination by the review panel would be considered a final decision and not subject to review by the Secretary. Given such a determination or a failure to make the determination within the 60-day deadline, the appellant would be able to request judicial review before a civil court. The filing deadline for this civil action would be within 60 days of the determination or within 60 days of the end of the deadline to make such determination. The venue for judicial review would be the U.S. District Court where the appellant is located, or where the greatest number of appellants is located, or in the district court for the District of Columbia. The amount in controversy (if any) would be subject to annual interest awarded to the prevailing party by the reviewing court. Interest (equal to the rate of interest on obligations issued for purchase by the Federal Supplementary Medical Insurance Trust Fund effective for the month that the civil action commences) would accrue beginning on the first day of the first month beginning after the filing deadline. The interest payments would not be deemed to be Medicare reimbursement. The provision for expedited access to judicial review would apply to an institution's appeal concerning program participation, provided that the same require-

ments are met (no entity in the administrative appeals process has the authority to decide the relevant question of law or regulation, and no material facts are in dispute). Remedies applied to assure quality of care in skilled nursing facilities (under Section 1819) would not be affected while such appeals are pending.

To the extent that any part of an appeal poses a factual dispute that is being adjudicated before an administrative tribunal, this provision would not authorize the severance of the legal issues from the underlying factual dispute.

This section is effective for appeals filed on or after October 1, 2003.

Section 203. Expedited review of certain provider agreement determinations

Section 1866(h) of the Social Security Act permits any institution or agency dissatisfied with a determination that it is not a provider (or that it can no longer be a provider) access to an administrative hearing and judicial review.

This section requires the Secretary to develop and implement a process under 1866(h) to expedite provider agreement determinations, including those instances where participation is terminated or other sanctions (including the denial of payment for new admissions or appointment of temporary management) against skilled nursing facilities have been imposed. Priority would be given to termination of provider agreements.

Increased appropriations from the Medicare Trust Funds in FY2003 and subsequently would be authorized to (1) reduce the average time for administrative decisions on appeals of provider agreement determinations by 50 percent; (2) increase the number of ALJs and their staff; and (3) educate the ALJs and their staff on long term care issues.

This section is effective upon enactment.

Section 204. Revisions to Medicare appeals process

Section 521 of BIPA (which is not yet implemented) amends Section 1869 to establish certain filing and decision making deadlines in Medicare's administrative appeals process. The Secretary is required to establish in regulation the time limits for requesting a hearing by the ALJ or DAB.

BIPA also established QIC reconsiderations as part of Medicare's administrative review process. A QIC is an entity or organization that is independent of any organization under contract with the Secretary that makes initial determinations and meets the established requirements for sufficient training and expertise in medical science and legal matters. To reconsider whether a service is reasonable and necessary, a QIC will employ a panel of physicians or other appropriate health care professionals to review the facts and the circumstances of the initial determination. This reconsideration is to be based on applicable information, including clinical experience, and medical, technical, and scientific evidence.

The BIPA provisions regarding appeals of Medicare's initial determinations become effective on or after October 1, 2002, and those applying to national coverage determinations become effective on or after October 1, 2001.

Section 1154 of the Social Security Act describes the required functions of utilization and quality control peer review organizations (PROs). These entities review, subject to the provisions of their contract, the professional activities of physicians, other practitioners, and institutional providers in rendering services to Medicare beneficiaries. Generally, PRO reviews focus on determining the reasonableness of care, the quality of care, and the appropriateness of the setting. These determinations are ordinarily binding for purposes of determining whether benefits should be paid.

Certain PRO review procedures have been established for inpatient hospital care. If a hospital determines, and the attending physician agrees, that a continued hospital stay for a Medicare beneficiary is no longer necessary, the hospital may provide the patient (or the patient's representative) a notice of noncoverage. If the attending physician does not agree with the hospital's determination that care is no longer necessary, the hospital may request the PRO to review the validity of its determination. If a Medicare beneficiary receives a Medicare notice of noncoverage and requests a PRO review, the PRO must review the determination and provide notice to the patient, hospital, and attending physician, regardless of the patient's financial liability for the continued stay. Certain deadlines, conditions, and other notice requirements are established for these PRO reviews of inpatient care discharges.

This section establishes a deadline of 90 days to complete an appeal record for an ALJ hearing and the subsequent DAB review, a deadline that starts the day the request for such action is filed. The appellant would be permitted to request an extension of the 90-day deadline for the ALJ hearing or the DAB review for good cause; the ALJ or the DAB may extend the deadline based on a finding of good cause. The mandated deadlines for the appeals process established elsewhere would begin on the date the record is complete. A record would be complete when an ALJ or the DAB has received written or testimonial evidence, written or oral arguments, the decision and record of any prior appeal, and other evidence determined to be necessary.

The provisions would establish that a written notice of an initial determination associated with a claims denial be provided. The notice would be written in a manner designed to be understood by the beneficiary and would include: (1) the reason for the decision and an appropriate summary of the evidence used to support the decision; (2) the procedures for obtaining additional information concerning the determination or redetermination; and (3) the notification of appeal rights and associated instructions. A summary of the clinical or scientific evidence used to support the determination would be provided upon request. This summary would be provided in a redetermination notice.

The provisions would amend the existing requirement that a reconsideration decision be written. The reconsideration decision would have to be written in a manner that could be understood by the beneficiary and would only need to include a detailed explanation of the decision to the extent appropriate. The requirement that the reconsideration decision include a notice of appeal rights and relevant instructions would also be established.

Comparable requirements would be extended to ALJ decisions. These decisions would have to be written in an understandable

manner and include the specific reasons for the decision, an appropriate summary of the evidence, and a notification of appeal rights and instructions.

Medical records of the individual would be included as part of the applicable information used by QICs in making reconsiderations. Otherwise qualified utilization and quality control peer review organizations (PROs) would be able to act as QICs.

To qualify as a QIC, an entity would be required to have sufficient medical, legal, and other expertise, including knowledge of the Medicare program as well as sufficient staffing and independence to make reconsiderations. A QIC would be required to assure that reviewers meet professional qualifications, independence, and compensation requirements. If the request for review indicates that the item or service was furnished (or was ordered to be furnished) by a physician, each reviewing professional shall be a physician. Subject to reasonable compensation requirements and other exceptions, entities and their professional reviewers would have to meet independence requirements and may not: (1) be a "related" party; (2) have a material familial, financial, or professional relationship with a related party; (3) have a conflict of interest with respect to a related party. A QIC's compensation would not exceed a reasonable level and would not be contingent on any decision by the QIC or by any reviewing professional. A reviewer's compensation from a QIC would not exceed a reasonable level and would not be contingent on any decision rendered by the reviewer. In this context, a related party to a Medicare case involving an individual beneficiary is (1) the Secretary; fiscal intermediary; carrier; any fiduciary, officer, director or employee of HHS or a Medicare contractor; (2) the individual or authorized representative; (3) the health professional, institution, or entity that provides or manufactures the item or service involved in the case; and (4) any other party with substantial interest in the case, as defined by regulation.

Individuals affiliated with a fiscal intermediary, carrier, or other contractor would be able to act as a QIC reviewer if (1) a non-affiliated individual is not reasonably available; (2) the affiliated individual is not involved in the provision of items or services of the case; (3) the fact of the affiliation is disclosed to the Secretary, the beneficiary, or the authorized representative and no one objects; and (4) the affiliated individual is not a direct employee and does not provide services exclusively, primarily, or on behalf of a Medicare contractor. Individuals with staff privileges at the institution where treatment occurs would be able to serve as a reviewer if the affiliation is disclosed without objection, subject to limits on compensation. Each reviewing professional shall be an allopathic or osteopathic physician or health care professional who (1) is appropriately credentialed or licensed in one or more states or (2) typically treats the condition, makes the diagnosis, or provides the treatment under review.

The effective date of BIPA provisions regarding appeals of initial determinations would be changed from on or after October 1, 2002 to on or after October 1, 2003; the effective date of BIPA provisions with respect to national coverage determinations would be changed from on or after October 1, 2001 to those made on or after October 1, 2002.

The provisions would modify Section 1154 of the Social Security Act. Individuals who receive a notice of termination of service or are discharged from a hospital during the transition period would be able to request, in writing or orally, an expedited review from a PRO. (In the case of a termination of service, a physician would need to certify that the failure to continue services is likely to place the individual's health at significant risk). The transition period would be defined for each PRO service area as beginning on the date when the last triennial PRO contract becomes effective in FY2002 and ending on the expiration date of the PRO contract in FY2006. The current references established in 1154(e) would be changed to broaden the scope of the PRO review to include the other expedited appeal rights for terminations of services created under BIPA. The Secretary would transfer the PRO hearing functions to the QICs as appropriate. An expedited determination or re-determination by a QIC would preclude review by a PRO, but the individual would be entitled to an ALJ hearing.

The qualification and compensation requirements for reviewers would apply to fiscal intermediaries and carriers as well as Medicare administrative contractors.

These provisions are effective as if included in BIPA, subject to the specified modifications.

Section 205. Hearing rights related to decisions by the Secretary to deny or not renew a medicare enrollment agreement

Under current law, providers and, to some extent suppliers, have access to certain appeal mechanisms if their application to participate in Medicare is denied or terminated. Section 1866(h) of the Social Security Act provides for a hearing and judicial review of that hearing for any institution or agency dissatisfied with a determination that it is not a provider (or that it can no longer be a provider). There is no statutory provision extending such judicial appeal rights to physicians, practitioners, facilities, or suppliers.

Providers of services, physicians, practitioners, facilities or suppliers whose application to enroll or reenroll has been denied and who are dissatisfied with the determination would be entitled to a hearing and judicial review of the determination under the procedures that currently apply to providers under section 1866(h).

This section applies to denials that occur after a date specified by the Secretary, but not later than one year after the date of enactment.

Section 206. Appeals by providers when there is no other party available

Under this section, a provider of services, physician, practitioner, facility, or supplier would be able to appeal any determination for a deceased beneficiary, if there are no other parties to appeal the determination, so long as the estate of the beneficiary or the beneficiary's family or heirs are not liable for increased out-of-pocket expenditures that might result from the decision.

This section applies to items and services furnished after enactment.

Section 207. Process for exceptions to national coverage determinations under special medical circumstances

This section would require the Secretary to establish a process where an individual with (1) a serious or life-threatening condition and (2) special medical circumstances that were not considered when forming the national coverage determination (NCD) may request an exception to a national coverage determination. Unlike the existing process established under BIPA, the new additional process would not be a challenge to the reasonableness of the NCD as a whole, but would make clear that the NCD did not apply to that individual. A panel of physicians or other health professionals would make or review an initial decision. An expedited review of these decisions would be available if certified as necessary by a physician. Requests for exceptions would be subject to review by the DAB and subsequent judicial review. If an exception is approved for an individual, the national coverage determination shall not be applied to the treatment for that individual by any Medicare administrative contractor. The Secretary would provide information on (1) national coverage determinations made in the past year and (2) how to get more information with respect to the national determinations in an annual publication.

This section is effective as if included in BIPA, as subsequently modified.

Section 208. Prior determination process for certain items and services

Medicare law prohibits payment for items and services that are not medically reasonable and necessary for the diagnosis or treatment of an illness or an injury. Under certain circumstances, Medicare will pay for noncovered services that have been provided if both the beneficiary and the provider of the services did not know and could not have reasonably been expected to know that Medicare payment would not be made for these services. However, in most circumstances, either the beneficiary or the provider will be liable in the event that Medicare does not cover an item or service. There are detailed rules on beneficiary and provider liability in the statute.

A provider may be held liable for providing uncovered services, if, for example, specific requirements are published by the Medicare contractor or the provider has received a denial or reduction of payment for the same or similar service. In cases where the provider believes that the service may not be covered as reasonable and necessary, the provider may limit his liability by providing an acceptable advance notice of Medicare's possible denial of payment (ABN) to the patient. The notice must be given in writing, in advance of providing the service; include the patient's name, date, and description of service as well as reasons why the service may not be covered; and must be signed and dated by the patient to indicate that the beneficiary will assume financial liability for the service if Medicare payment is denied or reduced. Currently, there is no way for a beneficiary or provider to find out in advance of an item or service being provided whether or not Medicare will cover that item or service for that particular beneficiary.

This section requires the Secretary to establish a process through regulation where certain categories of physicians and beneficiaries

can establish whether Medicare covers certain items and services before such services are provided. An eligible requestor would be either a physician, or a Medicare beneficiary who receives an advance beneficiary notice (ABN) from a provider or supplier. The provisions would establish (1) that such prior determinations would be binding on the Medicare contractor, absent fraud or misrepresentation of facts; (2) the right to redetermination in the case of a denial; (3) the applicability of existing deadlines with respect to those redeterminations; (4) that contractors' advance determinations (and redeterminations) are not subject to further administrative or judicial review; and (5) an individual retains all rights to usual administrative or judicial review after receiving the service or receiving a determination that a service would not be covered. This section also requires that whenever a physician requests a pre-service determination (or redetermination), beneficiaries must still receive a notice that includes information explaining the beneficiary's right to receive the service and request that a Medicare claim be submitted so that they can access the appeals process under section 1869. The Secretary must establish a process to allow for the processing of such requests beginning 18 months after enactment. The Secretary would be required to collect data on the advance determination notices provided and establish a beneficiary and provider outreach and education program on the use of ABNs and national coverage decisions. The GAO is required to report on the use of the advance beneficiary notice and prior determination process within 18 months of implementation of the process.

The process would be in place to address requests for advance determinations filed on or after 18 months from enactment.

Section 209. BIPA-related technical amendments and corrections

BIPA established an advisory process for national coverage determinations where panels of experts formed by advisory committees could forward their recommendations directly to the Secretary without prior approval from the advisory committee or the Executive Committee.

This section corrects the statutory reference in BIPA to the advisory committees by changing the reference to the Public Health Service Act to that of the Social Security Act. Other BIPA references would be changed from "policy" to "determinations" to match the language in the underlying Medicare statute.

This section is effective as if included in BIPA.

TITLE III—CONTRACTING REFORM

Section 301. Increased flexibility in Medicare administration

Section 1816 of the Social Security Act authorizes the Secretary to establish agreements with fiscal intermediaries nominated by different provider associations to make Medicare payments for health care services furnished by institutional providers. Section 1842 of the Act authorizes the Secretary to enter into contracts with health insurers (or carriers) to make Medicare payments to physicians, practitioners, and other health care suppliers. Section 1834(a)(12) of the Act authorizes separate regional carriers for the payment of durable medical equipment (DME) claims. Section 1893

authorizes the Secretary to contract for certain program safeguard activities under the Medicare Integrity Program (MIP).

Certain terms and conditions of the contracting agreements for fiscal intermediaries and carriers are specified in the Medicare statute. Medicare regulations coupled with long-standing agency practices have further limited the way that contracts for claims administration services can be established. Specifically, the contracts are awarded without full and open competition; generally must cover the range of claims processing and related activities; cannot be terminated without cause and without the opportunity for a public hearing; and incorporate cost-based, not performance-based, reimbursement methods with no incentive bonuses.

Certain functions and responsibilities of the fiscal intermediaries and carriers are specified in the statute as well. The Secretary may not require a carrier or intermediary match data obtained in its other activities with Medicare data in order to identify beneficiaries who have other insurance coverage as part of the Medicare Secondary Payer (MSP) program. With the exception of prior authorization of DME claims, an entity may not perform activities (or receive related payments) under a claims processing contract to the extent that the activities are carried out pursuant to a MIP contract. Performance standards with respect to the timeliness of reviews, fair hearings, reconsiderations, and exemption decisions are established as well.

A Medicare contract with an intermediary or carrier may require any of its employees certifying or making payments to provide a surety bond to the United States in an amount established by the Secretary. Neither the contractor nor the contractor's employee who certifies the amount of Medicare payments is liable for erroneous payments in the absence of gross negligence or intent to defraud the United States. Neither the contractor nor the contractor's employee who disburses payments is liable for erroneous payments in the absence of gross negligence or intent to defraud the United States, if such payments are based upon a voucher signed by the certifying employee.

This section would add Section 1874A to the Social Security Act, which would permit the Secretary to enter into contracts with any eligible entity to serve as a Medicare administrative contractor. These contractors would perform or secure the performance (through subcontracting) some or all of the following tasks: determine payment amounts; make payments; educate and assist beneficiaries; communicate with providers and suppliers; educate and offer technical assistance to providers; and perform additional functions as necessary. An entity eligible to enter into a contract with respect to the performance of a particular function or activity must (1) demonstrate capability to carry out such function; (2) comply with conflict of interest standards that are generally applicable to Federal acquisition and procurement; (3) have sufficient assets to financially support the performance of such functions; and (4) meet other requirements imposed by the Secretary. The claims processing jurisdiction of a Medicare administrative contractor would be determined by the scope of the contract awarded to the entity. Specifically, the Medicare administrative contractor that would perform a particular function or activity is the entity that has the contract for that activity for any given beneficiary, any given provider

of service, physician, practitioner, facility, or supplier, or class of such providers, physicians, practitioners, facilities, or suppliers.

The Federal Acquisition Regulation would apply to Medicare administration contracts, except to the extent inconsistent with a specific Medicare requirement. Except as provided in laws that are generally applicable to Federal acquisition and procurement, the Secretary would be required to use competitive procedures when entering into a Medicare administrative contract. The Secretary would be able to renew a contract for up to five years without regard to statutory requirements concerning competitive contracting if the entity has met or exceeded specified performance standards. The Secretary would be able to transfer functions among contractors without regard to any provision of law requiring competition. The Secretary would be required to (1) consider performance quality and (2) provide notice of such transfer (in the Federal Register or otherwise) that describes the transferred functions and includes contractor contact information.

This section requires the Secretary to (1) provide incentives for the Medicare administrative contractors to provide efficient, high-quality services; (2) develop performance standards with respect to each of the payment, provider service, and beneficiary service functions required of the contractors; and (3) develop standards for measuring the extent to which a contractor has met such requirements. The Secretary would be required to contract only with those entities that will perform efficiently and effectively; will meet standards for financial responsibility, legal authority and service quality among other pertinent matters; will agree to furnish timely and necessary data; and will maintain and provide access to necessary records and data.

The Committee believes beneficiaries and providers should play an important role in evaluating contractor performance. The Secretary would be required to publish performance requirements and measurement standards in the Federal Register and may include beneficiary and provider satisfaction (as measured by surveys) as one of the standards. The performance requirements (1) would be set forth in the contract between the Secretary and the appropriate Medicare contractor; (2) would be used to evaluate contractor performance; and (3) would be consistent with the contract's written statement of work. A Medicare administrative contract would contain provisions deemed necessary by the Secretary and may provide for advances of Medicare funds for the purposes of making payments to providers and suppliers. In developing contract performance requirements for Medicare administrative contractors, the Secretary would be required to consider the inclusion of the existing standards in effect for timeliness of reviews, fair hearings, reconsiderations, and exemption decisions.

The existing MSP provision would apply: the Secretary would not be able to require contractors to match their data with Medicare data for the purposes of identifying beneficiaries with other insurance coverage. The Secretary would assure that the activities of the Medicare administrative contractors do not duplicate the Medicare Integrity Program (MIP) functions except with respect to the prior authorization of durable medical equipment (DME). An entity with a MIP contract would not be treated as a Medicare administrative contractor solely by reason of the MIP contract.

A Medicare administrative contractor and any of its employees certifying or disbursing payments may be required to provide a surety bond to the United States in an amount established by the Secretary. The liability standard of gross negligence is retained. The contractor's employee who certifies the amount of Medicare payments is not liable for erroneous payments in the absence of gross negligence or intent to defraud the United States. The contractor's employee who disburses payments is not liable for erroneous payments in the absence of gross negligence or intent to defraud the United States, if such payments are based upon an authorization from the certifying employee and the authorization meets the internal control standards established by the GAO. The contractor is not liable for payments made by certifying or disbursing officers unless grossly negligent when supervising or selecting these officers. No Medicare administrative contractor, subcontractor, or employee would be held civilly liable under any federal, state, or county law for performing any duty, function or activity authorized by a valid Medicare administrative contract, providing due care was exercised in the performance of such duty. The Secretary would pay the Medicare administrative contractor, its employees, or their legal representatives for defending these contractors or employers in a civil action related to the performance of their contractual duties, provided due care was exercised in the performance of these duties. These payments would be equal to the reasonable amount of legal expenses incurred, as determined by the Secretary.

The provisions establish that the activities of fiscal intermediaries in administering Medicare would be conducted through contracts with Medicare administrative contractors. The provider nomination process and contracting specifications would be repealed. Certain performance standards with respect to the processing of clean claims would be retained. Certain annual reporting requirements concerning the contractor's overpayment recovery efforts would be retained.

The provisions would establish that the activities of carriers administering Medicare would be conducted through contracts with Medicare administrative contractors. Certain instructions including those pertaining to nursing facility payments, claims assignment, physician participation, overpayment recoveries, and billing by suppliers would be retained. Certain performance standards with respect to the processing of clean claims would be retained. Contracting specifications and other conforming changes would be established. The Secretary, not the contractor, would be responsible for taking necessary actions to assure that reasonable payments are made, for those made on both a cost and charge basis. The Secretary, not the contractor, would be responsible for maintaining a toll-free telephone number for beneficiaries to obtain information on participating suppliers. Carrier fair hearing requirements would be eliminated. (BIPA eliminated the carrier fair hearing step in the administrative appeals process). Certain annual reporting requirements concerning the contractor's overpayment recovery efforts would be retained.

The provisions would apply to contracts that are competitively bid on or after dates specified by the Secretary (but not later than two years after enactment). Until the provisions are effective, the terms and conditions of contracts that are in effect would remain

in effect until the date the contract is let out for competitive bidding. All Medicare administrative contracts would have to be competitively bid by October 1, 2008. The requirement that MIP contracts be awarded on a competitive basis would continue to apply and would be unaffected by the provisions in this section. All references to fiscal intermediaries or carriers would be deemed a reference to an appropriate Medicare administrative contractor once the contracting changes are effective.

The Secretary would submit a legislative proposal containing necessary conforming and technical amendments to the appropriate Congressional committees within six months of enactment. The Secretary would submit an implementation plan to Congress and the GAO one year before the intended implementation date. The GAO would evaluate the plan and include appropriate recommendations no later than six months after the plan is received. No later than October 1, 2006, the Secretary would be required to submit a status report to Congress including (1) the number of contracts that have been competitively bid; (2) the distribution of functions among contracts and contractors; (3) a timeline for transition to full competition; and (4) a description of changes to contractor oversight and management.

The Committee directs the Secretary's attention to the provision of the Balanced Budget Act of 1997 requiring CMS to designate no more than five regional carriers to process laboratory claims. This provision was passed in order to streamline the processing of laboratory claims and was to be implemented by July 1, 1999, but CMS has taken no action to date. In consultation with the clinical laboratory industry, CMS may consider other potential solutions, including the designation of a single carrier to process all claims of laboratory entities operating in more than one state. CMS is directed to report back to the Committee on Energy and Commerce within three months detailing the action it has taken to implement this directive.

This section is effective upon enactment.

Section 302. Requirements for information security

This section requires Medicare administrative contractors, that determine and make payments, to implement a contractor-wide information security program that meets the requirements imposed on Federal agencies to ensure the security, integrity, confidentiality, authenticity, and availability of operational data and systems supporting operations. An annual audit of the information security at each Medicare administrative contractor (1) would be performed by an independent entity that meets the independence requirements specified by the Inspector General (OIG) in HHS; and (2) would test the effectiveness of the information security techniques for an appropriate subset of the contractor's systems. An audit of new contractors (those that have not been fiscal intermediaries or carriers) would be required prior to the start of their performing Medicare payment functions. An audit of existing contractors (those that are now fiscal intermediaries and carriers) would be required to be completed within one year of enactment. The results of the audits would be reported promptly to the OIG, which will submit a report annually to Congress. These provisions

would be equally applicable to fiscal intermediaries and carriers as to Medicare administrative contractors.

This section is effective upon enactment.

TITLE IV—EDUCATION AND OUTREACH IMPROVEMENTS

Section 401. Provider education and technical assistance

Under current law, Medicare's provider education activities are funded through the program management appropriation and through the Education and Training component of the Medicare Integrity Program (MIP). Both claims processing contractors (fiscal intermediaries and carriers) and MIP contractors may undertake provider education activities.

This section would add Section 1889 to the Social Security Act, which would require the Secretary to (1) coordinate the educational activities provided through the Medicare administrative and MIP contractors and (2) submit an evaluation to Congress, no later than October 1, 2002, on actions taken to coordinate the funding of provider education.

The Secretary would also be required to implement a methodology to measure the specific claims payment error rates of each contractor. This methodology would apply to existing fiscal intermediaries and carriers in the same manner as it applies to Medicare administrative contractors. No later than October 1, 2002, the Secretary would submit to Congress a report that describes how the methodology would be used in assessing contractor performance and whether the methodology would be a basis for performance bonuses. This section requires the GAO to submit to Congress a report on the adequacy of the methodology, including recommendations as appropriate, by October 1, 2002.

By October 1, 2002, the Secretary and each contractor would be required to maintain an Internet site that provides answers to frequently asked questions in an easily accessible format as well as all Medicare and Medicare-related materials published by the Secretary or the contractor.

The provisions would authorize a \$35 million increase in Medicare appropriations starting in FY2003 to increase provider education and training and to improve the accuracy and quality of contractor information provided in response to written and telephone inquiries. In conducting training activities (which may include the provision of technical assistance), Medicare contractors would be required to take into consideration the special needs of small providers and suppliers. The provision defines a small provider as an institution with fewer than 25 full-time equivalents (FTEs) or a physician, practitioner, facility, or supplier with fewer than 10 FTEs.

A Medicare contractor would not be able to use attendance records at educational programs or information gathered during these programs to select or track candidates for audit or prepayment review. Nothing in this section or section 1893(g) shall be construed as preventing the disclosure by a Medicare contractor of information on attendance at educational activities for law enforcement purposes. Nothing in this section or section 1893(g) shall be construed as providing for the disclosure by a Medicare contractor of the claims processing screens or computer edits used for identi-

fyng claims that will be subject to review. Nothing in the proposed legislation would require Medicare administrative contractors to disclose information that would compromise pending law enforcement activities or reveal findings of law enforcement-related audits.

This section is effective upon enactment.

Section 402. Access to and prompt responses from Medicare administrative contractors

The Medicare statutory provisions generally instruct carriers to assist providers and others who furnish services in developing procedures relating to utilization practices and to serve as a channel of communication relating information on program administration. Fiscal intermediaries are generally instructed to (1) provide consultative services to institutions and other agencies to enable them to establish and maintain fiscal records necessary for program participation and payment and (2) serve as a center for any information as well as a channel for communication with providers.

This section requires the Secretary to develop a communication strategy with beneficiaries, providers of services, physicians, practitioners, facilities, and suppliers. Each Medicare administrative contractor would be required to (1) provide general written responses (which may be through electronic transmission) in a clear, concise and accurate manner to inquiries from beneficiaries, providers of services, physicians, practitioners, facilities and suppliers within 45 business days; and (2) maintain a toll-free telephone number where these interested parties may obtain billing, coding, claims, coverage, and other appropriate Medicare information. The Secretary would be required to establish and publish in the Federal Register standards to monitor the accuracy, consistency, and timeliness of information provided in response to written and telephone inquiries. The standards would also be used in contractors' performance evaluations. The Secretary would be able to directly monitor the quality of the information so provided. These provisions would also apply to existing fiscal intermediaries and carriers.

This section takes effect on October 1, 2002.

Section 403. Reliance on guidance

Under current law, there is no provision with respect to reliance on written guidance. However, under certain circumstances, overpayments are not recovered if the incorrect payment has been made with respect to an individual who is without fault or where the recovery would decrease payments to another person who is without fault.

Under this section, if (1) a provider of services, physician, practitioner, facility, or supplier follows written guidance (which may be transmitted electronically) provided by the Secretary or a Medicare contractor when furnishing an item or service and submitting a claim; (2) the Secretary finds that the circumstances relating to the furnished items and services have been accurately presented in writing to the contractor; (3) there is no indication of fraud or abuse; and (4) the guidance is inaccurate, then the provider of services, physician, practitioner, facility, or supplier would not be subject to any penalty or interest, if they reasonably relied on such guidance. The Secretary would retain the authority to determine

whether the guidance in the form of general responses to FAQs applied to the particular circumstance of the individual claim. This provision would not affect the waiver of certain types of overpayments already established in the Medicare statute.

This section is effective for penalties imposed on or after enactment.

Section 404. Facilitation of consistent information to providers

This section requires the Secretary to appoint an individual within HHS (who is not an advocate of any specific departmental policy) to (1) respond to complaints and grievances from providers of services, physicians, practitioners, facilities, and suppliers regarding inconsistent Medicare and Medicare-related requirements (such as peer review and other administrative provisions); and (2) facilitate an appropriate response from HHS or the appropriate Medicare contractor. The Committee recognizes that as specific functions are assigned to separate contractors, there is the possibility of conflicting interpretations of policy. In such cases, the Committee expects that the provider facilitator created by this section would help to resolve these conflicts. This individual is not intended to be the first stop for providers of services, physicians, practitioners, facilities, and suppliers with questions about the Medicare program. Instead, this individual is intended to be used as a resource after other attempts to resolve conflicting or inconsistent information have failed.

This section is effective upon enactment.

Section 405. Policy development regarding evaluation and management (E&M) documentation guidelines

This section would not permit the Secretary to implement any new documentation guidelines for evaluation and management (E&M) physician services unless the guidelines (1) are developed in collaboration with practicing physicians (both generalists and specialists) after assessment by the physician community; (2) based on a plan with deadlines for improving use of E&M codes; (3) are developed after completion of pilot projects to test modifications to the codes; (4) are found to meet the desired objectives; and (5) are preceded by the establishment (and concurrent implementation) of a program to educate the physician community. The Secretary would make changes to existing E&M guidelines to reduce paperwork burdens on physicians. This section requires the Secretary to modify E&M guidelines to (1) identify clinically relevant documentation; (2) decrease non-clinically pertinent documentation; (3) increase the reviewers' accuracy; and (4) educate the physicians and the reviewers.

The provisions would establish different pilot projects in specified settings that would (1) be voluntary; (2) last long enough (as determined by the Secretary) to educate physicians and contractors on E&M guidelines; and (3) be conducted in consultation with practicing physicians (both generalists and specialists) to allow for an assessment of E&M guidelines and their use. A range of different projects would be established, including at least one that (1) has a peer review method by physicians; (2) has an alternative method based on documented face-to-face patient time; (3) is in a rural area; (4) is outside a rural area; (5) is in a teaching setting; and

(6) is in a nonteaching setting. The projects would examine the effect of modified E&M guidelines on different types of physician practices in terms of the cost of compliance. Data collected under these projects would not be the basis for overpayment demands or post-payment audits. This limitation would apply only to claims filed as part of the pilot project and would last only for the duration of the projects and only as long as the provider is a participant in the pilot project. The Secretary would be required to submit periodic reports on the pilot projects to Congress.

This section is effective upon enactment.

Section 406. Beneficiary Outreach Demonstration Program; report on 1-800 MEDICARE number

This section requires the Secretary to establish a 3-year demonstration project where Medicare specialists who are HHS employees are placed in at least six SSA offices to advise and assist Medicare beneficiaries. The SSA offices would be those with a high-volume of visits by Medicare beneficiaries, at least two of which would be in rural areas. In the rural SSA offices, the Secretary would provide for the Medicare specialists to travel among local offices on a scheduled basis. The Secretary would be required to (1) evaluate the project with respect to beneficiary utilization, beneficiary satisfaction, and cost-effectiveness and (2) recommend whether the demonstration should be established on a permanent basis.

The GAO would be required to (1) monitor the adequacy, accuracy, and consistency of the information provided to Medicare beneficiaries through the toll-free 1-800 MEDICARE number and (2) examine the education and training of those providing the information via the toll-free number. This section requires that the GAO submit a report to Congress no later than one year from enactment.

This section is effective upon enactment.

Section 407. Provider enrollment applications

This section requires the Secretary to (1) establish in regulation deadlines for actions on applications for enrollment and reenrollment; (2) monitor the performance of Medicare administrative contractors in meeting the deadlines; and (3) consult with providers, physicians, practitioners, facilities, and suppliers before changing Medicare's enrollment forms. The consultation process would be required for provider enrollment forms that are changed on or after January 1, 2002.

This section is effective upon enactment.

TITLE V—REVIEW, RECOVERY, AND ENFORCEMENT REFORM

Section 501. Prepayment reviews

This section would require Medicare contractors who conduct random prepayment reviews to do so in accordance with a standard protocol developed by the Secretary. Contractors would not be able to initiate non-random payment reviews based on the initial self-identification by a provider of services, physician, practitioner, facility, or supplier of an improper billing practice unless there is a likelihood of a sustained or high level of payment error. The Secretary would be required to issue regulations establishing a con-

crete endpoint for prepayment review. The termination of prepayment review may vary based upon the differences in the circumstances triggering such a review. No provision would prevent the denial of payment for claims actually reviewed under random prepayment review or prevent a Medicare administrative contractor from requesting documentation for a limited sample of submitted claims to ensure that the previous practice is not continuing.

The regulations required under this section must be issued not later than one year after enactment. The use of a standard protocol applies to random prepayment audits conducted on or after a date specified by the Secretary (which cannot be later than one year after the date of enactment).

Section 502. Recovery of overpayments

There is no current statutory provision with respect to repayment plans. Section 1833(j) of the Social Security Act provides that interest accrues on underpayments or overpayments starting within 30 days of the date of the final determination of the accurate payment amount.

This section requires the Secretary to enter into a repayment plan at the request of a provider of services, physician, practitioner, facility, or supplier for the offset or repayment of an overpayment for a period of at least one year but no longer than three years if the provider of services, physician, practitioner, facility, or supplier meets certain standards. The provider of services, physician, practitioner, facility, or supplier may choose between offset and a repayment plan provided they meet the established standards. Not later than one year after enactment, the Secretary would be required to develop standards for the recovery of overpayments, which would consider reliance on guidance and financial hardship. The financial hardship standard would take into account the amount of the proposed recovery as a proportion of Medicare payments. The Secretary would not be required to establish a repayment plan if (1) there is reason to suspect that the provider of services, physician, practitioner, facility, or supplier may file bankruptcy or discontinue program participation; or (2) there is an indication of fraud or abuse. The Secretary would be allowed to seek immediate collection if payments including interest are not made as scheduled.

Upon enactment, the Secretary would not be able to initiate any overpayment recovery action if the provider of services, physician, practitioner, facility, or supplier has sought a reconsideration of the Medicare overpayment by a qualified independent contractor (QIC) until the date of the reconsideration decision. If QICs are not yet in place, the overpayment recovery would not be initiated until the date of a redetermination decision by a fiscal intermediary or a carrier. If monies have been offset or repaid, the Secretary would return those amounts plus applicable interest if the original overpayment determination is reversed. If such an overpayment determination is upheld, interest would accrue beginning on the date of the original overpayment notice. The interest amount would be the rate otherwise applicable for Medicare overpayments.

For audits initiated after enactment, Medicare contractors would be required to provide a written notice (which may be in electronic form) of the intent to conduct a post-payment audit to those se-

lected as audit candidates. Medicare contractors would be required to provide those who have been audited a full review and understandable explanation of the findings that: (1) permits the development of an appropriate corrective action plan; (2) provides information on appeal rights as well as consent settlements (which are at the discretion of the Secretary); and (3) provides for an opportunity to supply additional information to the contractor. Medicare contractors would be required to take into account the information provided on a timely basis. The provisions requiring notice of audit and findings would not apply if pending law enforcement activities would be compromised or findings of law enforcement-related audits would be revealed.

Not later than one year after enactment, the Secretary would be required to establish, in consultation with health care associations, a process under which classes of providers, physicians, practitioners, facilities, and suppliers would be notified when their Medicare contractor has identified specific billing codes that the class may be over-utilizing.

Not later than one year after enactment, the Secretary would be required to establish a standard methodology for Medicare contractors to use in selecting a probe sample of claims for a review of abnormal billing patterns.

The Secretary would be able to use a consent settlement to resolve a projected overpayment. Before entering into any consent settlements after the date of enactment, the Secretary would be required to communicate (1) in a non-threatening manner to a provider of services, physician, practitioner, facility, or supplier that, based on a preliminary evaluation of medical records, an overpayment may exist; (2) the nature of the identified problems; and (3) the necessary steps to address the problem. The Secretary would allow providers of services, physicians, practitioners, facilities, and suppliers 45 days to submit additional information concerning the claims that have been reviewed. After considering the additional information, the Secretary would provide notice and explanation of any remaining overpayment determination and would offer the opportunity for a statistically valid random sample (which would not waive appeal rights) or a consent settlement (based on a projection from a smaller sample of claims with a waiver of appeal rights) to resolve the overpayment amounts.

A Medicare contractor would not be able to use extrapolation to determine overpayment amounts for statistically valid random samples initiated after the date of enactment, unless, as determined by the Secretary, a sustained or high level of payment error exists or a documented educational intervention did not correct the payment error.

These provisions are effective upon enactment, unless otherwise specified.

Section 503. Process for correction of minor errors and omissions on claims without pursuing appeals process

This section requires the Secretary to develop, in consultation with appropriate Medicare contractors and health care associations, a process under which minor errors and omissions on claims can be corrected and the corrected claims resubmitted without appealing the claims denial.

The Committee intends that this provision cover home health claims (on a pre- or post-payment basis) that are inadvertently submitted prior to the time that a physician certification or recertification of a plan of care is signed and dated. The claim would be returned to the home health agency, which would be allowed to re-submit such claim in lieu of filing an appeal.

The process required by this section would be developed no later than one year after date of enactment.

Section 504. Program and payment exclusions

Under current law, the Secretary is required to exclude individuals and entities from participation in Federal health programs who are (1) convicted of a criminal offense related to health care delivery under Medicare or under State health programs; (2) convicted of a criminal offense related to patient abuse or neglect under Federal or State law; (3) convicted of a felony relating to fraud, theft, or financial misconduct relating to a health care program financed or operated by the Federal, State, or local government; or (4) convicted of a felony related to a controlled substance. At the request of a State, the Secretary is permitted to waive a program exclusion with respect to Medicare or Medicaid, but only for exclusions described in (1) above.

Under current law, Medicare will not cover services that are furnished by a beneficiary's immediate relative.

This section allows the administrator of a Federal health program to request a waiver of a program exclusion if the exclusion of a sole community physician or source of specialized services in a community would impose a hardship. This conforming change would extend the same waiver authority currently in Medicare and Medicaid to Federal health programs. In addition, waivers could be requested for Medicare, Medicaid, and Federal health programs with respect to all exclusions except those related to patient abuse or neglect.

The exclusions for Medicare coverage would be changed. Medicare would be permitted to cover the expenses of providers who furnish Medicare services to (and impose charges on) their parents. Medicare would also be permitted to cover services rendered by all immediate relatives of beneficiaries living in rural areas.

This section is effective for items and services furnished on or after January 1, 2003.

TITLE VI—EMTALA IMPROVEMENTS

Section 601. Payment for EMTALA-mandated screening and stabilization services

Under current law, Medicare requires participating hospitals that operate an emergency room to provide necessary screening and stabilization services to a patient in order to determine whether an emergency medical situation exists prior to asking about the insurance status of the patient.

Providers have reported that some Medicare contractors are looking at final diagnoses (not presenting symptoms) in applying local medical review policies (LMRPs) that match particular tests to particular diagnoses—if a test does not match a listed diagnosis, payment is denied. Other claims are reportedly being denied based on

LMRPs that set frequency limits for certain tests—if the test’s use in the emergency room exceeds a frequency limit, payment is denied.

Under this section, emergency room services provided to screen and stabilize a Medicare beneficiary would be evaluated as reasonable and necessary on the basis of the information available to the treating physician or practitioner at the time the services were ordered. This would include the patient’s presenting symptoms or complaint and not the patient’s principal diagnosis. The Secretary would not be able to consider the frequency with which the item or service was provided to the patient before or after the time of admission or visit.

This section applies to items and services furnished after January 1, 2002.

Section 602. Emergency Medical Treatment and Labor Act (EMTALA) Task Force

This section establishes a 23-member task force within HHS. In its January 2001 report entitled “The Emergency Medical Treatment and Labor Act: The Enforcement Process,” the OIG recommended that CMS establish an EMTALA technical advisory group that includes all EMTALA stakeholders. The members of the task force are selected by the CMS Administrator under specified requirements. The Task Force would comprise the following members: the CMS Administrator; the OIG; four regional CMS staff involved in EMTALA investigations; one CMS headquarters staff involved in EMTALA policy; two individuals who participate in PRO reviews of EMTALA violations; four hospital administrators who have EMTALA experience; eight practicing physicians with EMTALA experience; one consumer representative; and one practicing defense attorney specializing in EMTALA cases. The task force would be required to (1) elect a member to serve as chairperson; (2) schedule its first meeting at the direction of the Secretary and meet at least twice a year subsequently; (3) terminate three years after the date of its first meeting; and (4) be exempt from the Federal Advisory Committee Act. The Task Force would review EMTALA regulations; provide advice and recommendations to the Secretary; solicit public comments from interested parties; and disseminate information on the application of the EMTALA regulations.

This section is effective upon enactment.

Section 603. Notification of providers when EMTALA investigation closed

This section requires the Secretary to establish a procedure to notify hospitals and physicians when an EMTALA investigation is closed.

This section is effective upon enactment.

Section 604. Prior review by peer review organizations in EMTALA cases involving termination of participation

Under current law, hospitals that are found to be in violation of EMTALA requirements may face civil monetary penalties and termination of their provider agreements. After a state investigation of an EMTALA complaint, the CMS Regional Office may ask their

local peer review organization (PRO) to perform a 5-day review to obtain additional medical expertise. This review is discretionary. However, prior to imposing a civil monetary penalty, the Secretary is required to request that a PRO assess whether the involved beneficiary had an emergency condition that had not been stabilized and provide a report on its findings. Except in the case where a delay would jeopardize the health or safety of individuals, the Secretary provides a 60-day period for these requested PRO reviews.

In its January 2001 report entitled "The Emergency Medical Treatment and Labor Act: The Enforcement Process," the OIG recommended that CMS ensure that peer review occurs before a provider is terminated from the Medicare program for an EMTALA violation. This section makes the current discretionary PRO review process mandatory. It requires that the Secretary request a PRO review in those cases that involve a question of medical judgment before making a compliance determination that would terminate a hospital's Medicare participation. The current period of review for the discretionary review (five business days) applies except in the case where a delay would jeopardize the health and safety of individuals. The PRO shall provide a copy of the report of its findings to the hospital or physician, consistent with existing confidentiality requirements.

This section applies to terminations initiated on or after enactment.

TITLE VII—MISCELLANEOUS IMPROVEMENTS

Section 701. Methods for determining payment basis for new lab tests

Under current law, outpatient clinical diagnostic laboratory tests are paid on the basis of area-wide fee schedules. The law establishes a cap on the payment amounts, which is currently set at 74 percent of the median for all fee schedules for that test. The cap is set at 100 percent of the median for tests performed after January 1, 2001 that the Secretary determines are new tests for which no limitation amount has previously been established.

This section requires the Secretary to establish procedures (by regulation) for determining the basis for, and amount of, payments for new clinical diagnostic laboratory tests. New laboratory tests would be defined as those assigned a new HCFA Common Procedure Coding System (HCPCS) code on or after January 1, 2003. The Secretary, as part of this procedure, would be required to (1) provide a list (on an Internet site or other appropriate venue) of tests for which payments are being established in that year; (2) publish a notice of a meeting in the Federal Register on the day the list becomes available; (3) hold the public meeting no earlier than 30 days after the notice to receive public comments and recommendations; (4) take into account the comments, recommendations, and accompanying data in both proposed and final payment determinations. The Secretary would set forth the criteria for making these determinations; make public the available data considered in making such determinations; and could convene other public meetings as necessary.

Under these regulations, the Secretary shall develop the criteria to be applied in making determinations regarding whether the pay-

ment level for a test should be established using gap-filling or cross-walking methodologies, and how these methodologies will be used. Among other things, the criteria will address when it is appropriate to cross-walk a new test to a clinically similar test (and its corresponding payment level) for which a fee schedule amount has already been established. When cross-walking is not appropriate and gap-filling is used, the criteria shall explain how market data may be collected and analyzed to arrive at a fair and appropriate payment amount.

The intent of these provisions is also to improve stakeholder input under a transparent and predictable process. In the beginning of the process, a code shall be considered to be “substantially revised” if there is a substantive change to the definition of the test or procedure to which the code applies (such as the analyte used in the test, the methodology employed, the technological features of the test, or the measurement used in the test). Using the input CMS receives throughout the open, public process, CMS will develop and make available to the public final determinations, together with the rationale for each such determination, the data on which the determination is based, and responses to comments received from the public.

This section is effective upon enactment.

Section 702. One year delay in lock in procedures for Medicare+Choice plans

Under the provisions in the Balanced Budget Act of 1997, Medicare beneficiaries are able to enroll in a Medicare+Choice plan, change plans, or return to traditional fee-for-service Medicare at any point in the calendar year through 2001. After this transition period where beneficiaries are able to make and change elections on an ongoing basis, these elections will be made and changed only during an annual coordinated election period. There is also a 3-month period after making an election when a beneficiary can change their election. Additional election periods called “special election periods” will apply for newly eligible Medicare beneficiaries and beneficiaries who experience certain events.

December 31, 2001 is the last day of continuous open enrollment and disenrollment during which a beneficiary can change elections an unlimited number of times. January 1, 2002 is the first year in which elections become locked in. The first six months of 2002 are a transition period when a beneficiary can change election only once (other than an election during the coordinated annual election period or in the case of an event qualifying for a special election). Starting January 1, 2003, new elections become effective the first day of January following each election period. Each year there is a 3-month period when an individual can change her election one time. Otherwise, elections cannot be changed until the next annual coordinated election period (unless the beneficiary qualifies for a special enrollment period). Limited exceptions are provided.

This section delays the implementation of the Medicare+Choice lock in provision (which limits beneficiaries’ ability to enroll and disenroll in Medicare managed care plans) from FY2002 to FY2003.

This section is effective upon enactment.

The Committee is pleased that the Secretary has published a notice of proposed rulemaking to provide Medicare payment for clin-

ical psychology internship training programs that would not qualify under Medicare’s existing provider-operated criteria. The Committee notes that Congress has consistently urged the Secretary to initiate payment for the training of clinical psychologists since 1997. Supportive language has been included in conference reports accompanying Medicare legislation in 1999 (Report 106–479), and in 2000 (Senate Report 106–293).

The Committee is concerned, however, that a delay in the rule may mean that hospitals and institutions will reduce or eliminate psychology training programs and urges implementation of the rule as soon as possible. The Committee notes that clinical psychologists provide valuable and unique services to Medicare beneficiaries during their training. Regarding their training, clinical psychologists are distinguishable from other health care professionals in that they are the only doctoral level mental health professionals fully participating in Medicare whose clinical training is not currently reimbursed. In addition, their clinical internship training is entirely controlled, administered, supervised, evaluated, and certified by the hospital or institution, separately accredited, and distinct from any university training they receive. Clinical psychologists are hospital-based in the final stages of their training functioning in a parallel status to medical interns and residents, not medical nursing or health professional students. Where a clinical psychologist has clearly finished their educational curriculum and is training solely in the hospital setting, it is the intention of Congress that the hospital be reimbursed if that training is hospital-based.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

SOCIAL SECURITY ACT

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TITLE XI—GENERAL PROVISIONS, PEER REVIEW, AND ADMINISTRATIVE SIMPLIFICATION

* * * * *

PART A—GENERAL PROVISIONS

* * * * *

EXCLUSION OF CERTAIN INDIVIDUALS AND ENTITIES FROM PARTICIPATION IN MEDICARE AND STATE HEALTH CARE PROGRAMS

SEC. 1128. (a) * * *

* * * * *

(c) NOTICE, EFFECTIVE DATE, AND PERIOD OF EXCLUSION.—
(1) * * *

* * * * *

(3)(A) * * *

(B) **【Subject to subparagraph (G), in the case of an exclusion under subsection (a), the minimum period of exclusion shall be not less than five years, except that, upon the request of a State, the Secretary may waive the exclusion under subsection (a)(1) in the case of an individual or entity that is the sole community physician or sole source of essential specialized services in a community.】**
Subject to subparagraph (G), in the case of an exclusion under subsection (a), the minimum period of exclusion shall be not less than five years, except that, upon the request of the administrator of a Federal health care program (as defined in section 1128B(f)) who determines that the exclusion would impose a hardship on beneficiaries under that program, the Secretary may waive the exclusion under subsection (a)(1), (a)(3), or (a)(4) with respect to that program in the case of an individual or entity that is the sole community physician or sole source of essential specialized services in a community. The Secretary's decision whether to waive the exclusion shall not be reviewable.

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PART B—PEER REVIEW OF THE UTILIZATION AND QUALITY OF HEALTH CARE SERVICES

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FUNCTIONS OF PEER REVIEW ORGANIZATIONS

SEC. 1154. (a) * * *

* * * * *

(e)(1) * * *

* * * * *

(6)(A) *In applying this subsection during the transition period (described in subparagraph (C)), any reference in this subsection—*

(i) to a hospital is deemed a reference to a provider of services;

(ii) to inpatient hospital care or services is deemed a reference to services of such a provider of services;

(iii) a notice under paragraph (1) is deemed to include—

(I) a notice to discharge the individual from the provider of services; or

(II) a notice of termination of services by a provider of services, but only in the case in which a physician certifies that failure to continue the provision of such services is likely to place the individual's health at significant risk; and

(iv) an inpatient is deemed a reference to a patient.

(B) After the transition period, paragraphs (2) through (5) shall not apply.

(C) For purposes of this paragraph and section 1869(b)(1)(F)(ii), the transition period, with respect to an individual who resides in an area served by a peer review organization—

(i) begins on the date on which the last triennial contract with any peer review organization under this part becomes effective during 2002; and

(ii) ends on the date that the triennial contract under this part with the organization that serves such area expires in 2006.

* * * * *

RIGHT TO HEARING AND JUDICIAL REVIEW

SEC. 1155. Any beneficiary who is entitled to benefits under title XVIII, and, subject to section 1154(a)(3)(D), any practitioner or provider, who is dissatisfied with a determination made by a contracting peer review organization in conducting its review responsibilities under this part, shall be entitled to a reconsideration of such determination by the reviewing organization. Where the reconsideration is adverse to the beneficiary and where the matter in controversy is \$200 or more, such beneficiary shall be entitled to a hearing by the Secretary (to the same extent as beneficiaries under title II are entitled to a hearing by the Commissioner of Social Security under section 205(b)). For purposes of the preceding sentence, subsection (l) of section 205 shall apply, except that any reference in such subsection to the Commissioner of Social Security or the Social Security Administration shall be deemed a reference to the Secretary or the Department of Health and Human Services, respectively. Where the amount in controversy is \$2,000 or more, such beneficiary shall be entitled to judicial review of any final decision relating to a reconsideration described in this subsection. *In the case of a determination made under section 1154(e)(6)(A) during the period in which the provisions of subsection (b) of section 1869 (as added by section 521 of Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, as enacted into law by section 1(a)(6) of Public Law 106-554) are in effect, this section shall not apply but the individual shall be entitled to a hearing on the determination before an administrative law judge under such subsection (b) in the same manner as such section applies to a hearing under subsection (a) of such section 1869.*

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TITLE XVIII—HEALTH INSURANCE FOR THE AGED AND DISABLED

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PART A—HOSPITAL INSURANCE BENEFITS FOR THE AGED AND DISABLED

* * * * *

【USE OF PUBLIC AGENCIES OR PRIVATE ORGANIZATIONS TO FACILITATE PAYMENT TO PROVIDERS OF SERVICES】

PROVISIONS RELATING TO THE ADMINISTRATION OF PART A

SEC. 1816. 【(a) If any group or association of providers of services wishes to have payments under this part to such providers made through a national, State, or other public or private agency or organization and nominates such agency or organization for this purpose, the Secretary is authorized to enter into an agreement with such agency or organization providing for the determination

by such agency or organization (subject to the provisions of section 1878 and to such review by the Secretary as may be provided for by the agreement) of the amount of the payments required pursuant to this part to be made to such providers (and to providers assigned to such agency or organization under subsection (e)), and for the making of such payments by such agency or organization to such providers (and to providers assigned to such agency or organization under subsection (e)). Such agreement may also include provision for the agency or organization to do all or any part of the following: (1) to provide consultative services to institutions or agencies to enable them to establish and maintain fiscal records necessary for purposes of this part and otherwise to qualify as hospitals, extended care facilities, or home health agencies, and (2) with respect to the providers of services which are to receive payments through it (A) to serve as a center for, and communicate to providers, any information or instructions furnished to it by the Secretary, and serve as a channel of communication from providers to the Secretary; (B) to make such audits of the records of providers as may be necessary to insure that proper payments are made under this part; and (C) to perform such other functions as are necessary to carry out this subsection. As used in this title and part B of title XI, the term "fiscal intermediary" means an agency or organization with a contract under this section.

[(b) The Secretary shall not enter into or renew an agreement with any agency or organization under this section unless—

[(1) he finds—

[(A) after applying the standards, criteria, and procedures developed under subsection (f), that to do so is consistent with the effective and efficient administration of this part, and

[(B) that such agency or organization is willing and able to assist the providers to which payments are made through it under this part in the application of safeguards against unnecessary utilization of services furnished by them to individuals entitled to hospital insurance benefits under section 226, and the agreement provides for such assistance; and

[(2) such agency or organization agrees—

[(A) to furnish to the Secretary such of the information acquired by it in carrying out its agreement under this section, and

[(B) to provide the Secretary with access to all such data, information, and claims processing operations, as the Secretary may find necessary in performing his functions under this part.]

(a) *The administration of this part shall be conducted through contracts with medicare administrative contractors under section 1874A.*

(c)[(1) An agreement with any agency or organization under this section may contain such terms and conditions as the Secretary finds necessary or appropriate, may provide for advances of funds to the agency or organization for the making of payments by it under subsection (a), and shall provide for payment of so much of the cost of administration of the agency or organization as is determined by the Secretary to be necessary and proper for carrying out

the functions covered by the agreement. The Secretary shall provide that in determining the necessary and proper cost of administration, the Secretary shall, with respect to each agreement, take into account the amount that is reasonable and adequate to meet the costs which must be incurred by an efficiently and economically operated agency or organization in carrying out the terms of its agreement. The Secretary shall cause to have published in the Federal Register, by not later than September 1 before each fiscal year, data, standards, and methodology to be used to establish budgets for fiscal intermediaries under this section for that fiscal year, and shall cause to be published in the Federal Register for public comment, at least 90 days before such data, standards, and methodology are published, the data, standards, and methodology proposed to be used. The Secretary may not require, as a condition of entering into or renewing an agreement under this section or under section 1871, that a fiscal intermediary match data obtained other than in its activities under this part with data used in the administration of this part for purposes of identifying situations in which the provisions of section 1862(b) may apply.】

(2)(A) Each 【agreement under this section】 *contract under section 1874A that provides for making payments under this part* shall provide that payment shall be issued, mailed, or otherwise transmitted with respect to not less than 95 percent of all claims submitted under this title—

(i) * * *

* * * * *

(3)(A) Each 【agreement under this section】 *contract under section 1874A that provides for making payments under this part* shall provide that no payment shall be issued, mailed, or otherwise transmitted with respect to any claim submitted under this title within the applicable number of calendar days after the date on which the claim is received.

* * * * *

【(d) If the nomination of an agency or organization as provided in this section is made by a group or association of providers of services, it shall not be binding on members of the group or association which notify the Secretary of their election to that effect. Any provider may, upon such notice as may be specified in the agreement under this section with an agency or organization, withdraw its nomination to receive payments through such agency or organization. Any provider which has withdrawn its nomination, and any provider which has not made a nomination, may elect to receive payments from any agency or organization which has entered into an agreement with the Secretary under this section if the Secretary and such agency or organization agree to it.

【(e)(1) Notwithstanding subsections (a) and (d), the Secretary, after taking into consideration any preferences of providers of services, may assign or reassign any provider of services to any agency or organization which has entered into an agreement with him under this section, if he determines, after applying the standards, criteria, and procedures developed under subsection (f), that such assignment or reassignment would result in the more effective and efficient administration of this part.

[(2) Notwithstanding subsections (a) and (d), the Secretary may (subject to the provisions of paragraph (4)) designate a national or regional agency or organization which has entered into an agreement with him under this section to perform functions under the agreement with respect to a class of providers of services in the Nation or region (as the case may be), if he determines, after applying the standards, criteria, and procedures developed under subsection (f), that such designation would result in more effective and efficient administration of this part.

[(3)(A) Before the Secretary makes an assignment or reassignment under paragraph (1) of a provider of services to other than the agency or organization nominated by the provider, he shall furnish (i) the provider and such agency or organization with a full explanation of the reasons for his determination as to the efficiency and effectiveness of the agency or organization to perform the functions required under this part with respect to the provider, and (ii) such agency or organization with opportunity for a hearing, and such determination shall be subject to judicial review in accordance with chapter 7 of title 5, United States Code.

[(B) Before the Secretary makes a designation under paragraph (2) with respect to a class of providers of services, he shall furnish (i) such providers and the agencies and organizations adversely affected by such designation with a full explanation of the reasons for his determination as to the efficiency and effectiveness of such agencies and organizations to perform the functions required under this part with respect to such providers, and (ii) the agencies and organizations adversely affected by such designation with opportunity for a hearing, and such determination shall be subject to judicial review in accordance with chapter 7 of title 5, United States Code.

[(4) Notwithstanding subsections (a) and (d) and paragraphs (1), (2), and (3) of this subsection, the Secretary shall designate regional agencies or organizations which have entered into an agreement with him under this section to perform functions under such agreement with respect to home health agencies (as defined in section 1861(o)) in the region, except that in assigning such agencies to such designated regional agencies or organizations the Secretary shall assign a home health agency which is a subdivision of a hospital (and such agency and hospital are affiliated or under common control) only if, after applying such criteria relating to administrative efficiency and effectiveness as he shall promulgate, he determines that such assignment would result in the more effective and efficient administration of this title. By not later than July 1, 1987, the Secretary shall limit the number of such regional agencies or organizations to not more than ten.

[(5) Notwithstanding any other provision of this title, the Secretary shall designate the agency or organization which has entered into an agreement under this section to perform functions under such an agreement with respect to each hospice program, except that with respect to a hospice program which is a subdivision of a provider of services (and such hospice program and provider of services are under common control) due regard shall be given to the agency or organization which performs the functions under this section for the provider of services.

[(f)(1) In order to determine whether the Secretary should enter into, renew, or terminate an agreement under this section with an agency or organization, whether the Secretary should assign or reassign a provider of services to an agency or organization, and whether the Secretary should designate an agency or organization to perform services with respect to a class of providers of services, the Secretary shall develop standards, criteria, and procedures to evaluate such agency's or organization's (A) overall performance of claims processing (including the agency's or organization's success in recovering payments made under this title for services for which payment has been or could be made under a primary plan (as defined in section 1862(b)(2)(A))) and other related functions required to be performed by such an agency or organization under an agreement entered into under this section, and (B) performance of such functions with respect to specific providers of services, and the Secretary shall establish standards and criteria with respect to the efficient and effective administration of this part. No agency or organization shall be found under such standards and criteria not to be efficient or effective or to be less efficient or effective solely on the ground that the agency or organization serves only providers located in a single State.

[(2) The standards and criteria established under paragraph (1) shall include—

[(A) with respect to claims for services furnished under this part by any provider of services other than a hospital—

[(i) whether such agency or organization is able to process 75 percent of reconsiderations within 60 days (except in the case of fiscal year 1989, 66 percent of reconsiderations) and 90 percent of reconsiderations within 90 days, and

[(ii) the extent to which such agency's or organization's determinations are reversed on appeal; and

[(B) with respect to applications for an exemption from or exception or adjustment to the target amount applicable under section 1886(b) to a hospital that is not a subsection (d) hospital (as defined in section 1886(d)(1)(B))—

[(i) if such agency or organization receives a completed application, whether such agency or organization is able to process such application not later than 75 days after the application is filed, and

[(ii) if such agency or organization receives an incomplete application, whether such agency or organization is able to return the application with instructions on how to complete the application not later than 60 days after the application is filed.

[(g) An agreement with the Secretary under this section may be terminated—

[(1) by the agency or organization which entered into such agreement at such time and upon such notice to the Secretary, to the public, and to the providers as may be provided in regulations, or

[(2) by the Secretary at such time and upon such notice to the agency or organization, to the providers which have nominated it for purposes of this section, and to the public, as may be provided in regulations, but only if he finds, after applying

the standards, criteria, and procedures developed under subsection (f) and after reasonable notice and opportunity for hearing to the agency or organization, that (A) the agency or organization has failed substantially to carry out the agreement, or (B) the continuation of some or all of the functions provided for in the agreement with the agency or organization is disadvantageous or is inconsistent with the efficient administration of this part.

[(h) An agreement with an agency or organization under this section may require any of its officers or employees certifying payments or disbursing funds pursuant to the agreement, or otherwise participating in carrying out the agreement, to give surety bond to the United States in such amount as the Secretary may deem appropriate.

[(i)(1) No individual designated pursuant to an agreement under this section as a certifying officer shall, in the absence of gross negligence or intent to defraud the United States, be liable with respect to any payments certified by him under this section.

[(2) No disbursing officer shall, in the absence of gross negligence or intent to defraud the United States, be liable with respect to any payment by him under this section if it was based upon a voucher signed by a certifying officer designated as provided in paragraph (1) of this subsection.

[(3) No such agency or organization shall be liable to the United States for any payments referred to in paragraph (1) or (2).]

(j) [An agreement with an agency or organization under this section] *A contract with a medicare administrative contractor under section 1874A with respect to the administration of this part* shall require that, with respect to a claim for home health services, extended care services, or post-hospital extended care services submitted by a provider to [such agency or organization] *such medicare administrative contractor* that is denied, [such agency or organization] *such medicare administrative contractor—*

(1) furnish the provider and the individual with respect to whom the claim is made with a written explanation of the denial and of the statutory or regulatory basis for the denial; and

(2) in the case of a request for reconsideration of a denial, promptly notify such individual and the provider of the disposition of such reconsideration.

(k) [An agreement with an agency or organization under this section] *A contract with a medicare administrative contractor under section 1874A with respect to the administration of this part* shall require that [such agency or organization] *such medicare administrative contractor* submit an annual report to the Secretary describing the steps taken to recover payments made for items or services for which payment has been or could be made under a primary plan (as defined in section 1862(b)(2)(A)).

[(l) No agency or organization may carry out (or receive payment for carrying out) any activity pursuant to an agreement under this section to the extent that the activity is carried out pursuant to a contract under the Medicare Integrity Program under section 1893.]

FEDERAL HOSPITAL INSURANCE TRUST FUND

SEC. 1817. (a) * * *

* * * * *

(k) HEALTH CARE FRAUD AND ABUSE CONTROL ACCOUNT.—

(1) * * *

* * * * *

(4) APPROPRIATED AMOUNTS TO ACCOUNT FOR MEDICARE INTEGRITY PROGRAM.—

(A) IN GENERAL.—There are hereby appropriated to the Account from the Trust Fund for each fiscal year such amounts as are necessary to carry out the Medicare Integrity Program under section 1893[~~1~~], subject to subparagraph (B)] and functions described in subparagraph (C)(ii), subject to subparagraphs (B) and (C) and to be available without further appropriation.

(B) AMOUNTS SPECIFIED.—[The amount appropriated] Subject to subparagraph (C), the amount appropriated under subparagraph (A) for a fiscal year is as follows:

(i) * * *

* * * * *

(C) ENHANCED PROVIDER EDUCATION AND TRAINING.—

(i) IN GENERAL.—In addition to the amount appropriated under subparagraph (B), the amount appropriated under subparagraph (A) for a fiscal year (beginning with fiscal year 2003) is increased by \$35,000,000.

(ii) USE.—The funds made available under this subparagraph shall be used only to increase the conduct by medicare contractors of education and training of providers of services, physicians, practitioners, facilities, and suppliers regarding billing, coding, and other appropriate items and may also be used to improve the accuracy, consistency, and timeliness of contractor responses to written and phone inquiries from providers of services, physicians, practitioners, facilities, and suppliers.

* * * * *

PART B—SUPPLEMENTARY MEDICAL INSURANCE BENEFITS FOR THE AGED AND DISABLED

* * * * *

PAYMENT OF BENEFITS

SEC. 1833. (a) * * *

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(h)(1) * * *

* * * * *

(8)(A) The Secretary shall establish by regulation procedures for determining the basis for, and amount of, payment under this subsection for any clinical diagnostic laboratory test with respect to which a new or substantially revised HCPCS code is assigned on

or after January 1, 2003 (in this paragraph referred to as “new tests”).

(B) Determinations under subparagraph (A) shall be made only after the Secretary—

(i) makes available to the public (through an Internet site and other appropriate mechanisms) a list that includes any such test for which establishment of a payment amount under this subsection is being considered for a year;

(ii) on the same day such list is made available, causes to have published in the *Federal Register* notice of a meeting to receive comments and recommendations (and data on which recommendations are based) from the public on the appropriate basis under this subsection for establishing payment amounts for the tests on such list;

(iii) not less than 30 days after publication of such notice convenes a meeting, that includes representatives of officials of the Centers for Medicare & Medicaid Services involved in determining payment amounts, to receive such comments and recommendations (and data on which the recommendations are based);

(iv) taking into account the comments and recommendations (and accompanying data) received at such meeting, develops and makes available to the public (through an Internet site and other appropriate mechanisms) a list of proposed determinations with respect to the appropriate basis for establishing a payment amount under this subsection for each such code, together with an explanation of the reasons for each such determination, the data on which the determinations are based, and a request for public written comments on the proposed determination; and

(v) taking into account the comments received during the public comment period, develops and makes available to the public (through an Internet site and other appropriate mechanisms) a list of final determinations of the payment amounts for such tests under this subsection, together with the rationale for each such determination, the data on which the determinations are based, and responses to comments and suggestions received from the public.

(C) Under the procedures established pursuant to subparagraph (A), the Secretary shall—

(i) set forth the criteria for making determinations under subparagraph (A); and

(ii) make available to the public the data (other than proprietary data) considered in making such determinations.

(D) The Secretary may convene such further public meetings to receive public comments on payment amounts for new tests under this subsection as the Secretary deems appropriate.

(E) For purposes of this paragraph:

(i) The term “HCPCS” refers to the Health Care Procedure Coding System.

(ii) A code shall be considered to be “substantially revised” if there is a substantive change to the definition of the test or procedure to which the code applies (such as a new analyte or a

new methodology for measuring an existing analyte-specific test).

* * * * *

【USE OF CARRIERS FOR ADMINISTRATION OF BENEFITS】

PROVISIONS RELATING TO THE ADMINISTRATION OF PART B

SEC. 1842. **【(a)** In order to provide for the administration of the benefits under this part with maximum efficiency and convenience for individuals entitled to benefits under this part and for providers of services and other persons furnishing services to such individuals, and with a view to furthering coordination of the administration of the benefits under part A and under this part, the Secretary is authorized to enter into contracts with carriers, including carriers with which agreements under section 1816 are in effect, which will perform some or all of the following functions (or, to the extent provided in such contracts, will secure performance thereof by other organizations); and, with respect to any of the following functions which involve payments for physicians' services on a reasonable charge basis, the Secretary shall to the extent possible enter into such contracts:

【(1)(A) make determinations of the rates and amounts of payments required pursuant to this part to be made to providers of services and other persons on a reasonable cost or reasonable charge basis (as may be applicable);

【(B) receive, disburse, and account for funds in making such payments; and

【(C) make such audits of the records of providers of services as may be necessary to assure that proper payments are made under this part;

【(2)(A) determine compliance with the requirements of section 1861(k) as to utilization review; and

【(B) assist providers of services and other persons who furnish services for which payment may be made under this part in the development of procedures relating to utilization practices, make studies of the effectiveness of such procedures and methods for their improvement, assist in the application of safeguards against unnecessary utilization of services furnished by providers of services and other persons to individuals entitled to benefits under this part, and provide procedures for and assist in arranging, where necessary, the establishment of groups outside hospitals (meeting the requirements of section 1861(k)(2)) to make reviews of utilization;

【(3) serve as a channel of communication of information relating to the administration of this part; and

【(4) otherwise assist, in such manner as the contract may provide, in discharging administrative duties necessary to carry out the purposes of this part.】

(a) The administration of this part shall be conducted through contracts with medicare administrative contractors under section 1874A.

(b)【(1) Contracts with carriers under subsection (a) may be entered into without regard to section 3709 of the Revised Statutes or any other provision of law requiring competitive bidding.】

(2) [(A) No such contract shall be entered into with any carrier unless the Secretary finds that such carrier will perform its obligations under the contract efficiently and effectively and will meet such requirements as to financial responsibility, legal authority, and other matters as he finds pertinent. The Secretary shall publish in the Federal Register standards and criteria for the efficient and effective performance of contract obligations under this section, and opportunity shall be provided for public comment prior to implementation. In establishing such standards and criteria, the Secretary shall provide a system to measure a carrier's performance of responsibilities described in paragraph (3)(H), subsection (h), and section 1845(e)(2). The Secretary may not require, as a condition of entering into or renewing a contract under this section or under section 1871, that a carrier match data obtained other than in its activities under this part with data used in the administration of this part for purposes of identifying situations in which section 1862(b) may apply.]

[(B) The Secretary shall establish standards for evaluating carriers' performance of reviews of initial carrier determinations and of fair hearings under paragraph (3)(C), under which a carrier is expected—

[(i) to complete such reviews, within 45 days after the date of a request by an individual enrolled under this part for such a review, in 95 percent of such requests, and

[(ii) to make a final determination, within 120 days after the date of receipt of a request by an individual enrolled under this part for a fair hearing under paragraph (3)(C), in 90 percent of such cases.]

(C) In the case of residents of nursing facilities who receive services described in clause (i) or (ii) of section 1861(s)(2)(K) performed by a member of a team, the Secretary shall instruct [carriers] *medicare administrative contractors* to develop mechanisms which permit routine payment under this part for up to 1.5 visits per month per resident. In the previous sentence, the term "team" refers to a physician and includes a physician assistant acting under the supervision of the physician or a nurse practitioner working in collaboration with that physician, or both.

[(D) In addition to any other standards and criteria established by the Secretary for evaluating carrier performance under this paragraph relating to avoiding erroneous payments, the carrier shall be subject to standards and criteria relating to the carrier's success in recovering payments made under this part for items or services for which payment has been or could be made under a primary plan (as defined in section 1862(b)(2)(A)).]

[(E) With respect to the payment of claims for home health services under this part that, but for the amendments made by section 4611 of the Balanced Budget Act of 1997, would be payable under part A instead of under this part, the Secretary shall continue administration of such claims through fiscal intermediaries under section 1816.]

(3) [Each such contract shall provide that the carrier] *The Secretary*—

(A) [will] *shall* take such action as may be necessary to assure that, where payment under this part for a service is on

a cost basis, the cost is reasonable cost (as determined under section 1861(v));

(B) **will** shall take such action as may be necessary to assure that, where payment under this part for a service is on a charge basis, such charge will be reasonable and not higher than the charge applicable, for a comparable service and under comparable circumstances, **to the policyholders and subscribers of the carrier** to the policyholders and subscribers of the medicare administrative contractor, and such payment will (except as otherwise provided in section 1870(f)) be made—

(i) * * *

* * * * *

(C) will establish and maintain procedures pursuant to which an individual enrolled under this part will be granted an opportunity for a fair hearing by the carrier, in any case where the amount in controversy is at least \$100, but less than \$500, when requests for payment under this part with respect to services furnished him are denied or are not acted upon with reasonable promptness or when the amount of such payment is in controversy;

(D) will furnish to the Secretary such timely information and reports as he may find necessary in performing his functions under this part;

(E) will maintain such records and afford such access thereto as the Secretary finds necessary to assure the correctness and verification of the information and reports under subparagraph (D) and otherwise to carry out the purposes of this part;

(F) **will** shall take such action as may be necessary to assure that where payment under this part for a service rendered is on a charge basis, such payment shall be determined on the basis of the charge that is determined in accordance with this section on the basis of customary and prevailing charge levels in effect at the time the service was rendered or, in the case of services rendered more than 12 months before the year in which the bill is submitted or request for payment is made, on the basis of such levels in effect for the 12-month period preceding such year;

(G) **will** shall, for a service that is furnished with respect to an individual enrolled under this part, that is not paid on an assignment-related basis, and that is subject to a limiting charge under section 1848(g)—

(i) * * *

* * * * *

(H) **if it makes determinations or payments with respect to physicians' services, will** shall implement—

(i) programs to recruit and retain physicians as participating physicians in the area served by the **carrier** medicare administrative contractor, including educational and outreach activities and the use of professional relations personnel to handle billing and other problems relating to payment of claims of participating physicians; and

* * * * *

[(I) will submit annual reports to the Secretary describing the steps taken to recover payments made under this part for items or services for which payment has been or could be made under a primary plan (as defined in section 1862(b)(2)(A)); and]

(L) [will] *shall* monitor and profile physicians' billing patterns within each area or locality and provide comparative data to physicians whose utilization patterns vary significantly from other physicians in the same payment area or locality[;]. [and shall contain such other terms and conditions not inconsistent with this section as the Secretary may find necessary or appropriate.] In determining the reasonable charge for services for purposes of this paragraph, there shall be taken into consideration the customary charges for similar services generally made by the physician or other person furnishing such services, as well as the prevailing charges in the locality for similar services. No charge may be determined to be reasonable in the case of bills submitted or requests for payment made under this part after December 31, 1970, if it exceeds the higher of (i) the prevailing charge recognized by the carrier and found acceptable by the Secretary for similar services in the same locality in administering this part on December 31, 1970, or (ii) the prevailing charge level that, on the basis of statistical data and methodology acceptable to the Secretary, would cover 75 percent of the customary charges made for similar services in the same locality during the 12-month period ending on the June 30 last preceding the start of the calendar year in which the service is rendered. In the case of physicians' services the prevailing charge level determined for purposes of clause (ii) of the preceding sentence for any twelve-month period (beginning after June 30, 1973) specified in clause (ii) of such sentence may not exceed (in the aggregate) the level determined under such clause for the fiscal year ending June 30, 1973, or (with respect to physicians' services furnished in a year after 1987) the level determined under this sentence (or under any other provision of law affecting the prevailing charge level) for the previous year except to the extent that the Secretary finds, on the basis of appropriate economic index data, that such higher level is justified by year-to-year economic changes. With respect to power-operated wheelchairs for which payment may be made in accordance with section 1861(s)(6), charges determined to be reasonable may not exceed the lowest charge at which power-operated wheelchairs are available in the locality. In the case of medical services, supplies, and equipment (including equipment servicing) that, in the judgment of the Secretary, do not generally vary significantly in quality from one supplier to another, the charges incurred after December 31, 1972, determined to be reasonable may not exceed the lowest charge levels at which such services, supplies, and equipment are widely and consistently available in a locality except to the extent and under the circumstances specified by the Secretary. The requirement in subparagraph (B) that a bill be submitted or request for payment be made by the close of the following calendar year shall not apply if (I) failure to submit the bill or request the payment by the close of such year is due to the error or misrepresentation of an officer, employee, fiscal intermediary, carrier, *medicare administrative contractor*, or agent of the Department of Health and Human Services

performing functions under this title and acting within the scope of his or its authority, and (II) the bill is submitted or the payment is requested promptly after such error or misrepresentation is eliminated or corrected. Notwithstanding the provisions of the third and fourth sentences preceding this sentence, the prevailing charge level in the case of a physician service in a particular locality determined pursuant to such third and fourth sentences for any calendar year after 1974 shall, if lower than the prevailing charge level for the fiscal year ending June 30, 1975, in the case of a similar physician service in the same locality by reason of the application of economic index data, be raised to such prevailing charge level for the fiscal year ending June 30, 1975, and shall remain at such prevailing charge level until the prevailing charge for a year (as adjusted by economic index data) equals or exceeds such prevailing charge level. The amount of any charges for outpatient services which shall be considered reasonable shall be subject to the limitations established by regulations issued by the Secretary pursuant to section 1861(v)(1)(K), and in determining the reasonable charge for such services, the Secretary may limit such reasonable charge to a percentage of the amount of the prevailing charge for similar services furnished in a physician's office, taking into account the extent to which overhead costs associated with such outpatient services have been included in the reasonable cost or charge of the facility.

* * * * *

[(5) Each contract under this section shall be for a term of at least one year, and may be made automatically renewable from term to term in the absence of notice by either party of intention to terminate at the end of the current term; except that the Secretary may terminate any such contract at any time (after such reasonable notice and opportunity for hearing to the carrier involved as he may provide in regulations) if he finds that the carrier has failed substantially to carry out the contract or is carrying out the contract in a manner inconsistent with the efficient and effective administration of the insurance program established by this part.]

(6) No payment under this part for a service provided to any individual shall (except as provided in section 1870) be made to anyone other than such individual or (pursuant to an assignment described in subparagraph (B)(ii) of paragraph (3)) the physician or other person who provided the service, except that (A) payment may be made (i) to the employer of such physician or other person if such physician or other person is required as a condition of his employment to turn over his fee for such service to his employer, or (ii) (where the service was provided in a hospital, critical access hospital, clinic, or other facility) to the facility in which the service was provided if there is a contractual arrangement between such physician or other person and such facility under which such facility submits the bill for such service, (B) payment may be made to an entity (i) which provides coverage of the services under a health benefits plan, but only to the extent that payment is not made under this part, (ii) which has paid the person who provided the service an amount (including the amount payable under this part) which that person has accepted as payment in full for the service, and (iii) to which the individual has agreed in writing that pay-

ment may be made under this part, (C) in the case of services described in clause (i) of section 1861(s)(2)(K), payment shall be made to either (i) the employer of the physician assistant involved, or (ii) with respect to a physician assistant who was the owner of a rural health clinic (as described in section 1861(aa)(2)) for a continuous period beginning prior to the date of the enactment of the Balanced Budget Act of 1997 and ending on the date that the Secretary determines such rural health clinic no longer meets the requirements of section 1861(aa)(2), payment may be made directly to the physician assistant, (D) payment may be made to a physician for physicians' services (and services furnished incident to such services) furnished by a second physician to patients of the first physician if (i) the first physician is unavailable to provide the services; (ii) the services are furnished pursuant to an arrangement between the two physicians that (I) is informal and reciprocal, or (II) involves per diem or other fee-for-time compensation for such services; (iii) the services are not provided by the second physician over a continuous period of more than 60 days; and (iv) the claim form submitted to the [carrier] *medicare administrative contractor* for such services includes the second physician's unique identifier (provided under the system established under subsection (r)) and indicates that the claim meets the requirements of this subparagraph for payment to the first physician, (E) in the case of an item or service (other than services described in section 1888(e)(2)(A)(ii)) furnished by, or under arrangements made by, a skilled nursing facility to an individual who (at the time the item or service is furnished) is a resident of a skilled nursing facility, payment shall be made to the facility, (F) in the case of home health services (including medical supplies described in section 1861(m)(5), but excluding durable medical equipment to the extent provided for in such section) furnished to an individual who (at the time the item or service is furnished) is under a plan of care of a home health agency, payment shall be made to the agency (without regard to whether or not the item or service was furnished by the agency, by others under arrangement with them made by the agency, or when any other contracting or consulting arrangement, or otherwise), and (G) in the case of services in a hospital or clinic to which section 1880(e) applies, payment shall be made to such hospital or clinic. No payment which under the preceding sentence may be made directly to the physician or other person providing the service involved (pursuant to an assignment described in subparagraph (B)(ii) of paragraph (3)) shall be made to anyone else under a reassignment or power of attorney (except to an employer or facility as described in clause (A) of such sentence); but nothing in this subsection shall be construed (i) to prevent the making of such a payment in accordance with an assignment from the individual to whom the service was provided or a reassignment from the physician or other person providing such service if such assignment or reassignment is made to a governmental agency or entity or is established by or pursuant to the order of a court of competent jurisdiction, or (ii) to preclude an agent of the physician or other person providing the service from receiving any such payment if (but only if) such agent does so pursuant to an agency agreement under which the compensation to be paid to the agent for his services for or in connection with the billing or collection of payments due such physician or other

person under this title is unrelated (directly or indirectly) to the amount of such payments or the billings therefor, and is not dependent upon the actual collection of any such payment. For purposes of subparagraph (C) of the first sentence of this paragraph, an employment relationship may include any independent contractor arrangement, and employer status shall be determined in accordance with the law of the State in which the services described in such clause are performed.

(7)(A) In the case of physicians' services furnished to a patient in a hospital with a teaching program approved as specified in section 1861(b)(6) but which does not meet the conditions described in section 1861(b)(7), [the carrier] *the Secretary* shall not provide (except on the basis described in subparagraph (C)) for payment for such services under this part—

(i) * * *

* * * * *

(B) The customary charge for such services in a hospital shall be determined in accordance with regulations issued by the Secretary and taking into account the following factors:

(i) In the case of a physician who is not a teaching physician (as defined by the Secretary), [the carrier] *the Secretary* shall take into account the amounts the physician charges for similar services in the physician's practice outside the teaching setting.

(ii) In the case of a teaching physician, if the hospital, its physicians, or other appropriate billing entity has established one or more schedules of charges which are collected for medical and surgical services, [the carrier] *the Secretary* shall base payment under this title on the greatest of—

(I) * * *

* * * * *

(C) In the case of physicians' services furnished to a patient in a hospital with a teaching program approved as specified in section 1861(b)(6) but which does not meet the conditions described in section 1861(b)(7), if the conditions described in subclauses (I) and (II) of subparagraph (A)(i) are met and if the physician elects payment to be determined under this subparagraph, [the carrier] *the Secretary* shall provide for payment for such services under this part on the basis of regulations of the Secretary governing reimbursement for the services of hospital-based physicians (and not on any other basis).

* * * * *

(c)(1) Any contract entered into with a carrier under this section shall provide for advances of funds to the carrier for the making of payments by it under this part, and shall provide for payment of the cost of administration of the carrier, as determined by the Secretary to be necessary and proper for carrying out the functions covered by the contract. The Secretary shall provide that in determining a carrier's necessary and proper cost of administration, the Secretary shall, with respect to each contract, take into account the amount that is reasonable and adequate to meet the costs which must be incurred by an efficiently and economically operated carrier in carrying out the terms of its contract. The Secretary shall

cause to have published in the Federal Register, by not later than September 1 before each fiscal year, data, standards, and methodology to be used to establish budgets for carriers under this section for that fiscal year, and shall cause to be published in the Federal Register for public comment, at least 90 days before such data, standards, and methodology are published, the data, standards, and methodology proposed to be used.】

(2)(A) Each 【contract under this section which provides for the disbursement of funds, as described in subsection (a)(1)(B),】 *contract under section 1874A that provides for making payments under this part* shall provide that payment shall be issued, mailed, or otherwise transmitted with respect to not less than 95 percent of all claims submitted under this part—

(i) * * *

* * * * *

(3)(A) Each contract under this section which provides for the disbursement of funds, as described in 【subsection (a)(1)(B)】 *section 1874A(a)(3)(B)*, shall provide that no payment shall be issued, mailed, or otherwise transmitted with respect to any claim submitted under this title within the applicable number of calendar days after the date on which the claim is received.

* * * * *

(4) Neither a 【carrier】 *medicare administrative contractor* nor the Secretary may impose a fee under this title—

(A) * * *

* * * * *

(5) Each 【contract under this section which provides for the disbursement of funds, as described in subsection (a)(1)(B), shall require the carrier】 *contract under section 1874A that provides for making payments under this part shall require the medicare administrative contractor* to meet criteria developed by the Secretary to measure the timeliness of 【carrier responses】 *contractor responses* to requests for payment of items described in section 1834(a)(15)(C).

【(6) No carrier may carry out (or receive payment for carrying out) any activity pursuant to a contract under this subsection to the extent that the activity is carried out pursuant to a contract under the Medicare Integrity Program under section 1893. The previous sentence shall not apply with respect to the activity described in section 1893(b)(5) (relating to prior authorization of certain items of durable medical equipment under section 1834(a)(15)).】

【(d) Any contract with a carrier under this section may require such carrier or any of its officers or employees certifying payments or disbursing funds pursuant to the contract, or otherwise participating in carrying out the contract, to give surety bond to the United States in such amount as the Secretary may deem appropriate.】

【(e)(1) No individual designated pursuant to a contract under this section as a certifying officer shall, in the absence of gross negligence or intent to defraud the United States, be liable with respect to any payments certified by him under this section.】

【(2) No disbursing officer shall, in the absence of gross negligence or intent to defraud the United States, be liable with re-

spect to any payment by him under this section if it was based upon a voucher signed by a certifying officer designated as provided in paragraph (1) of this subsection.

[(3) No such carrier shall be liable to the United States for any payments referred to in paragraph (1) or (2).

[(f) For purposes of this part, the term "carrier" means—

[(1) with respect to providers of services and other persons, a voluntary association, corporation, partnership, or other non-governmental organization which is lawfully engaged in providing, paying for, or reimbursing the cost of, health services under group insurance policies or contracts, medical or hospital service agreements, membership or subscription contracts, or similar group arrangements, in consideration of premiums or other periodic charges payable to the carrier, including a health benefits plan duly sponsored or underwritten by an employee organization; and

[(2) with respect to providers of services only, any agency or organization (not described in paragraph (1)) with which an agreement is in effect under section 1816.]

(g) The Railroad Retirement Board shall, in accordance with such regulations as the Secretary may prescribe, contract with a [carrier or carriers] *medicare administrative contractor or contractors* to perform the functions set out in this section with respect to individuals entitled to benefits as qualified railroad retirement beneficiaries pursuant to section 226(a) of this Act and section 7(d) of the Railroad Retirement Act of 1974.

(h)(1) * * *

(2) [(a)] Each carrier having an agreement with the Secretary under subsection (a) *The Secretary* shall maintain a toll-free telephone number or numbers at which individuals enrolled under this part may obtain the names, addresses, specialty, and telephone numbers of participating physicians and suppliers and may request a copy of an appropriate directory published under paragraph (4). [(b)] Each such carrier *The Secretary* shall, without charge, mail a copy of such directory upon such a request.

(3)(A) In any case in which [a carrier having an agreement with the Secretary under subsection (a)] *medicare administrative contractor having a contract under section 1874A that provides for making payments under this part* is able to develop a system for the electronic transmission to such carrier of bills for services, [such carrier] *such contractor* shall establish direct lines for the electronic receipt of claims from participating physicians and suppliers.

(B) The Secretary shall establish a procedure whereby an individual enrolled under this part may assign, in an appropriate manner on the form claiming a benefit under this part for an item or service furnished by a participating physician or supplier, the individual's rights of payment under a medicare supplemental policy (described in section 1882(g)(1)) in which the individual is enrolled. In the case such an assignment is properly executed and a payment determination is made by [a carrier] *a medicare administrative contractor* with a contract under this section, [the carrier] *the contractor* shall transmit to the private entity issuing the medicare supplemental policy notice of such fact and shall include an explanation of benefits and any additional information that the Sec-

retary may determine to be appropriate in order to enable the entity to decide whether (and the amount of) any payment is due under the policy. The Secretary may enter into agreements for the transmittal of such information to entities electronically. The Secretary shall impose user fees for the transmittal of information under this subparagraph by **[a carrier]** *a medicare administrative contractor*, whether electronically or otherwise, and such user fees shall be collected and retained by **[the carrier]** *the contractor*.

* * * * *

(5)(A) The Secretary shall promptly notify individuals enrolled under this part through an annual mailing of the participation program under this subsection and the publication and availability of the directories and shall make the appropriate area directory or directories available in each district and branch office of the Social Security Administration, in the offices of **[carriers]** *medicare administrative contractors*, and to senior citizen organizations.

(B) The annual notice provided under subparagraph (A) shall include—

(i) * * *

* * * * *

(iii) an explanation of the assistance offered by **[carriers]** *medicare administrative contractors* in obtaining the names of participating physicians and suppliers, and

* * * * *

(1)(1)(A) Subject to subparagraph (C), if—

(i) * * *

* * * * *

(iii)(I) a **[carrier]** *medicare administrative contractor* determines under this part or a peer review organization determines under part B of title XI that payment may not be made by reason of section 1862(a)(1) because a service otherwise covered under this title is not reasonable and necessary under the standards described in that section or (II) payment under this title for such services is denied under section 1154(a)(2) by reason of a determination under section 1154(a)(1)(B), and

* * * * *

(2) Each **[carrier]** *medicare administrative contractor* with a contract in effect under this section with respect to physicians and each peer review organization with a contract under part B of title XI shall send any notice of denial of payment for physicians' services based on section 1862(a)(1) and for which payment is not requested on an assignment-related basis to the physician and the individual involved.

* * * * *

(p)(1) * * *

* * * * *

(3) In the case of a request for payment for an item or service furnished by a physician not submitted on an assignment-related basis and which does not include the code (or codes) required under paragraph (1)—

(A) if the physician knowingly and willfully fails to provide the code (or codes) promptly upon request of the Secretary or a **carrier** *medicare administrative contractor*, the physician may be subject to a civil money penalty in an amount not to exceed \$2,000, and

* * * * *

(q)(1)(A) The Secretary, in consultation with groups representing physicians who furnish anesthesia services, shall establish by regulation a relative value guide for use in all **carrier** localities in making payment for physician anesthesia services furnished under this part. Such guide shall be designed so as to result in expenditures under this title for such services in an amount that would not exceed the amount of such expenditures which would otherwise occur.

* * * * *

PART C—MEDICARE+CHOICE PROGRAM

ELIGIBILITY, ELECTION, AND ENROLLMENT

SEC. 1851. (a) * * *

* * * * *

(e) COVERAGE ELECTION PERIODS.—

(1) * * *

(2) OPEN ENROLLMENT AND DISENROLLMENT OPPORTUNITIES.—Subject to paragraph (5)—

(A) CONTINUOUS OPEN ENROLLMENT AND DISENROLLMENT **THROUGH 2001** *THROUGH 2002*.—At any time during 1998, 1999, 2000, **and 2001** *2001, and 2002*, a Medicare+Choice eligible individual may change the election under subsection (a)(1).

(B) CONTINUOUS OPEN ENROLLMENT AND DISENROLLMENT FOR FIRST 6 MONTHS **DURING 2002** *DURING 2003*.—

(i) IN GENERAL.—Subject to clause (ii) and subparagraph (D), at any time during the first 6 months of **2002** *2003*, or, if the individual first becomes a Medicare+Choice eligible individual during **2002** *2003*, during the first 6 months during **2002** *2003* in which the individual is a Medicare+Choice eligible individual, a Medicare+Choice eligible individual may change the election under subsection (a)(1).

* * * * *

(C) CONTINUOUS OPEN ENROLLMENT AND DISENROLLMENT FOR FIRST 3 MONTHS IN SUBSEQUENT YEARS.—

(i) IN GENERAL.—Subject to clause (ii) and subparagraph (D), at any time during the first 3 months of a year after **2002** *2003*, or, if the individual first becomes a Medicare+Choice eligible individual during a year after **2002** *2003*, during the first 3 months of such year in which the individual is a Medicare+Choice eligible individual, a Medicare+

Choice eligible individual may change the election under subsection (a)(1).

* * * * *

(D) CONTINUOUS OPEN ENROLLMENT FOR INSTITUTIONALIZED INDIVIDUALS.—At any time after **[2001]** 2002 in the case of a Medicare+Choice eligible individual who is institutionalized (as defined by the Secretary), the individual may elect under subsection (a)(1)—

- (i) to enroll in a Medicare+Choice plan; or
- (ii) to change the Medicare+Choice plan in which the individual is enrolled.

* * * * *

(4) SPECIAL ELECTION PERIODS.—Effective as of January 1, **[2002]** 2003, an individual may discontinue an election of a Medicare+Choice plan offered by a Medicare+Choice organization other than during an annual, coordinated election period and make a new election under this section if—

(A) * * *

* * * * *

Effective as of January 1, **[2002]** 2003, an individual who, upon first becoming eligible for benefits under part A at age 65, enrolls in a Medicare+Choice plan under this part, the individual may discontinue the election of such plan, and elect coverage under the original fee-for-service plan, at any time during the 12-month period beginning on the effective date of such enrollment.

* * * * *

BENEFITS AND BENEFICIARY PROTECTIONS

SEC. 1852. (a) BASIC BENEFITS.—

(1) * * *

(2) SATISFACTION OF REQUIREMENT.—

(A) * * *

(2) Section 1852(a)(2)(C) (42 U.S.C. 1395w-22(a)(2)(C)) is amended by striking “policy” and inserting “determination” both places it appears.

* * * * *

(C) ELECTION OF UNIFORM COVERAGE **[POLICY]** DETERMINATION.—In the case of a Medicare+Choice organization that offers a Medicare+Choice plan in an area in which more than one local coverage **[policy]** determination is applied with respect to different parts of the area, the organization may elect to have the local coverage **[policy]** determination for the part of the area that is most beneficial to Medicare+Choice enrollees (as identified by the Secretary) apply with respect to all Medicare+Choice enrollees enrolled in the plan.

* * * * *

PART D—MISCELLANEOUS PROVISIONS

* * * * *

EXCLUSIONS FROM COVERAGE AND MEDICARE AS SECONDARY PAYER

SEC. 1862. (a) Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services—

(1) * * *

* * * * *

(11) where such expenses constitute charges imposed by immediate relatives (*other than a child*) of such individual or members of his household, *unless the items or services are furnished in a rural area (as defined in section 1886(d)(2)(D))*;

* * * * *

Paragraph (7) shall not apply to Federally qualified health center services described in section 1861(aa)(3)(B). In making a national coverage determination (as defined in paragraph (1)(B) of section 1869(f)) the Secretary shall ensure that the public is afforded notice and opportunity to comment prior to implementation by the Secretary of the determination; meetings of advisory committees established under **[section 1114(f)]** *section 222 of the Public Health Service Act* with respect to the determination are made on the record; in making the determination, the Secretary has considered applicable information (including clinical experience and medical, technical, and scientific evidence) with respect to the subject matter of the determination; and in the determination, provide a clear statement of the basis for the determination (including responses to comments received from the public), the assumptions underlying that basis, and make available to the public the data (other than proprietary data) considered in making the determination.

* * * * *

(d) *For purposes of subsection (a)(1)(A), in the case of any item or service that is required to be provided pursuant to section 1867 to an individual who is entitled to benefits under this title, determinations as to whether the item or service is reasonable and necessary shall be made on the basis of the information available to the treating physician or practitioner (including the patient's presenting symptoms or complaint) at the time the item or service was ordered or furnished by the physician or practitioner (and not on the patient's principal diagnosis). When making such determinations with respect to such an item or service, the Secretary shall not consider the frequency with which the item or service was provided to the patient before or after the time of the admission or visit.*

* * * * *

[(i)] (j)(1) Any advisory committee appointed under **[subsection (f)]** *section 222 of the Public Health Service Act* to advise the Secretary on matters relating to the interpretation, application, or implementation of **[section 1862(a)(1)]** *subsection (a)(1)* shall assure the full participation of a nonvoting member in the deliberations of the advisory committee, and shall provide such nonvoting member access to all information and data made available to voting members of the advisory committee, other than information that—

(A) is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section (relating to trade secrets); or

(B) the Secretary determines would present a conflict of interest relating to such nonvoting member.

(2) If an advisory committee described in paragraph (1) organizes into panels of experts according to types of items or services considered by the advisory committee, any such panel of experts may report any recommendation with respect to such items or services directly to the Secretary without the prior approval of the advisory committee or an executive committee thereof.

* * * * *

AGREEMENTS WITH PROVIDERS OF SERVICES; ENROLLMENT PROCESSES

SEC. 1866. (a) * * *

* * * * *

(h)(1)(A) Except as provided in paragraph (2), an institution or agency dissatisfied with a determination by the Secretary that it is not a provider of services or with a determination described in subsection (b)(2) shall be entitled to a hearing thereon by the Secretary (after reasonable notice) to the same extent as is provided in section 205(b), and to judicial review of the Secretary's final decision after such hearing as is provided in section 205(g), except that, in so applying such sections and in applying section 205(1) thereto, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.

(B) An institution or agency described in subparagraph (A) that has filed for a hearing under subparagraph (A) shall have expedited access to judicial review under this subparagraph in the same manner as providers of services, suppliers, and beneficiaries may obtain expedited access to judicial review under the process established under section 1869(b)(2). Nothing in this subparagraph shall be construed to affect the application of any remedy imposed under section 1819 during the pendency of an appeal under this subparagraph.

* * * * *

(j) HEARING RIGHTS IN CASES OF DENIAL OR NON-RENEWAL.—A provider of services, physician, practitioner, facility, or supplier whose application to enroll (or, if applicable, to renew enrollment) under this title is denied may have a hearing and judicial review of such denial under the procedures that apply under subsection (h)(1)(A) to a provider of services that is dissatisfied with a determination by the Secretary.

EXAMINATION AND TREATMENT FOR EMERGENCY MEDICAL CONDITIONS AND WOMEN IN LABOR

SEC. 1867. (a) * * *

* * * * *

(d) ENFORCEMENT.—

(1) * * *

* * * * *

(3) CONSULTATION WITH PEER REVIEW ORGANIZATIONS.—In considering allegations of violations of the requirements of this section in imposing sanctions under paragraph (1) or in terminating a hospital's participation under this title, the Secretary shall request the appropriate utilization and quality control peer review organization (with a contract under part B of title XI) to assess whether the individual involved had an emergency medical condition which had not been stabilized, and provide a report on its findings. Except in the case in which a delay would jeopardize the health or safety of individuals, the Secretary shall request such a review before effecting a sanction under paragraph (1) and shall provide a period of at least 60 days for such review. *Except in the case in which a delay would jeopardize the health or safety of individuals, the Secretary shall also request such a review before making a compliance determination as part of the process of terminating a hospital's participation under this title for violations related to the appropriateness of a medical screening examination, stabilizing treatment, or an appropriate transfer as required by this section, and shall provide a period of 5 business days for such review. The organization shall provide of copy of the report on its findings to the hospital or physician consistent with confidentiality requirements imposed on the organization under such part B.*

(4) NOTICE UPON CLOSING AN INVESTIGATION.—*The Secretary shall establish a procedure to notify hospitals and physicians when an investigation under this section is closed.*

* * * * *

The text of existing law for section 1869 is shown to reflect the amendments made to that section by Public Law 106-554, effective October 1, 2002.

DETERMINATIONS; APPEALS

SEC. 1869. (a) INITIAL DETERMINATIONS.—

(1) * * *

* * * * *

(4) REQUIREMENTS OF NOTICE OF DETERMINATIONS AND REDETERMINATIONS.—*A written notice of a determination on an initial determination or on a redetermination, insofar as such determination or redetermination results in a denial of a claim for benefits, shall be provided in printed form and written in a manner calculated to be understood by the beneficiary and shall include—*

(A) *the specific reasons for the determination, including, as appropriate—*

(i) *upon request in the case of an initial determination, a summary of the clinical or scientific evidence used in making the determination; and*

(ii) *in the case of a redetermination, such a summary;*

(B) *the procedures for obtaining additional information concerning the determination or redetermination; and*

(C) *notification of the right to seek a redetermination or otherwise appeal the determination and instructions on*

how to initiate such a redetermination or appeal under this section.

(b) APPEAL RIGHTS.—

(1) IN GENERAL.—

(A) RECONSIDERATION OF INITIAL DETERMINATION.—Subject to subparagraph (D), any individual dissatisfied with any initial determination under subsection (a)(1) shall be entitled to reconsideration of the determination, and, subject to subparagraphs (D) and (E), a hearing thereon by the Secretary to the same extent as is provided in section 205(b) and, *subject to paragraph (2)*, to judicial review of the Secretary’s final decision after such hearing as is provided in section 205(g). For purposes of the preceding sentence, any reference to the “Commissioner of Social Security” or the “Social Security Administration” in subsection (g) or (1) of section 205 shall be considered a reference to the “Secretary” or the “Department of Health and Human Services”, respectively.

* * * * *

(F) EXPEDITED PROCEEDINGS.—

(i) * * *

【(ii) EXPEDITED HEARING.—In a hearing by the Secretary under this section, in which the moving party alleges that no material issues of fact are in dispute, the Secretary shall make an expedited determination as to whether any such facts are in dispute and, if not, shall render a decision expeditiously.】

(ii) NO APPLICATION DURING TRANSITION PERIOD.—*Clause (i) shall not apply during the transition period described in section 1154(e)(6)(C).*

* * * * *

(2) EXPEDITED ACCESS TO JUDICIAL REVIEW.—

(A) IN GENERAL.—*The Secretary shall establish a process under which a provider of services or supplier that furnishes an item or service or a beneficiary who has filed an appeal under paragraph (1) may obtain access to judicial review when a review panel (described in subparagraph (D)), on its own motion or at the request of the appellant, determines that the Departmental Appeals Board does not have the authority to decide the question of law or regulation relevant to the matters in controversy and that there is no material issue of fact in dispute. The appellant may make such request only once with respect to a question of law or regulation for a specific matter in dispute in a case of an appeal.*

(B) PROMPT DETERMINATIONS.—*If, after or coincident with appropriately filing a request for an administrative hearing, the appellant requests a determination by the appropriate review panel that the Departmental Appeals Board does not have the authority to decide the question of law or regulations relevant to the matters in controversy and that there is no material issue of fact in dispute and if such request is accompanied by the documents and materials as the appropriate review panel shall require for pur-*

poses of making such determination, such review panel shall make a determination on the request in writing within 60 days after the date such review panel receives the request and such accompanying documents and materials. Such a determination by such review panel shall be considered a final decision and not subject to review by the Secretary.

(C) ACCESS TO JUDICIAL REVIEW.—

(i) IN GENERAL.—If the appropriate review panel—

(I) determines that there are no material issues of fact in dispute and that the only issue is one of law or regulation that the Departmental Appeals Board does not have authority to decide; or

(II) fails to make such determination within the period provided under subparagraph (B);

then the appellant may bring a civil action as described in this subparagraph.

(ii) DEADLINE FOR FILING.—Such action shall be filed, in the case described in—

(I) clause (i)(I), within 60 days of the date of the determination described in such subparagraph; or

(II) clause (i)(II), within 60 days of the end of the period provided under subparagraph (B) for the determination.

(iii) VENUE.—Such action shall be brought in the district court of the United States for the judicial district in which the appellant is located (or, in the case of an action brought jointly by more than one applicant, the judicial district in which the greatest number of applicants are located) or in the district court for the District of Columbia.

(iv) INTEREST ON ANY AMOUNTS IN CONTROVERSY.—Where a provider of services or supplier seeks judicial review pursuant to this paragraph, the amount in controversy (if any) shall be subject to annual interest beginning on the first day of the first month beginning after the 60-day period as determined pursuant to clause (ii) and equal to the rate of interest on obligations issued for purchase by the Federal Supplementary Medical Insurance Trust Fund for the month in which the civil action authorized under this paragraph is commenced, to be awarded by the reviewing court in favor of the prevailing party. No interest awarded pursuant to the preceding sentence shall be deemed income or cost for the purposes of determining reimbursement due providers of services and suppliers under this Act.

(D) REVIEW PANEL DEFINED.—For purposes of this subsection, a “review panel” is a panel of 3 members from the Departmental Appeals Board, selected for the purpose of making determinations under this paragraph.

(3) TIMELY COMPLETION OF THE RECORD.—

(A) DEADLINE.—Subject to subparagraph (B), the deadline to complete the record in a hearing before an administrative law judge or a review by the Departmental Appeals

Board is 90 days after the date the request for the appeal is filed.

(B) *EXTENSIONS FOR GOOD CAUSE.*—The person filing a request under subparagraph (A) may request an extension of such deadline for good cause. The administrative law judge, in the case of a hearing, and the Departmental Appeals Board in the case of a review, may extend such deadline based upon a finding of good cause to a date specified by such individual.

(C) *DELAY IN DECISION DEADLINES UNTIL COMPLETION OF RECORD.*—Notwithstanding any other provision of this section, the deadlines otherwise established under subsection (d) for the making of determinations in hearings or review under this section shall begin on the date on which the record is complete.

(D) *COMPLETE DESCRIBED.*—For purposes of this paragraph, a record is complete when the administrative law judge, in the case of a hearing, or the Departmental Appeals Board, in the case of a review, has received—

- (i) written or testimonial evidence, or both, submitted by the person filing the request,
- (ii) written or oral argument, or both, is presented,
- (iii) the decision of, and the record for, the prior level of appeal,
- (iv) such other evidence as such judge or Board, as the case may be, determines is required to make a determination on the request.

(c) *CONDUCT OF RECONSIDERATIONS BY INDEPENDENT CONTRACTORS.*—

(1) * * *

(2) *QUALIFIED INDEPENDENT CONTRACTOR.*—For purposes of this subsection, the term “qualified independent contractor” means an entity or organization that (*except in the case of a utilization and quality control peer review organization, as defined in section 1152*) is independent of any organization under contract with the Secretary that makes initial determinations under subsection (a)(1), and that meets the requirements established by the Secretary consistent with paragraph (3) [.] and meets the following requirements:

(A) *GENERAL REQUIREMENTS.*—

(i) *The entity or organization has (directly or through contracts or other arrangements) sufficient medical, legal, and other expertise (including knowledge of the program under this title) and sufficient staffing to carry out duties of a qualified independent contractor under this section on a timely basis.*

(ii) *The entity or organization has provided assurances that it will conduct activities consistent with the applicable requirements of this section, including that it will not conduct any activities in a case unless the independence requirements of subparagraph (B) are met with respect to the case.*

(iii) *The entity or organization meets such other requirements as the Secretary provides by regulation.*

(B) *INDEPENDENCE REQUIREMENTS.*—

(i) *IN GENERAL.*—Subject to clause (ii), an entity or organization meets the independence requirements of this subparagraph with respect to any case if the entity—

(I) is not a related party (as defined in subsection (g)(5));

(II) does not have a material familial, financial, or professional relationship with such a party in relation to such case; and

(III) does not otherwise have a conflict of interest with such a party (as determined under regulations).

(ii) *EXCEPTION FOR REASONABLE COMPENSATION.*—Nothing in clause (i) shall be construed to prohibit receipt by a qualified independent contractor of compensation from the Secretary for the conduct of activities under this section if the compensation is provided consistent with clause (iii).

(iii) *LIMITATIONS ON ENTITY COMPENSATION.*—Compensation provided by the Secretary to a qualified independent contractor in connection with reviews under this section shall—

(I) not exceed a reasonable level; and

(II) not be contingent on any decision rendered by the contractor or by any reviewing professional.

(3) *REQUIREMENTS.*—Any qualified independent contractor entering into a contract with the Secretary under this subsection shall meet all of the following requirements:

(A) *IN GENERAL.*—The qualified independent contractor shall perform such duties and functions and assume such responsibilities as may be required by the Secretary to carry out the provisions of this subsection, and shall have sufficient training and expertise in medical science and legal matters to make reconsiderations under this subsection.

(B) *RECONSIDERATIONS.*—

(i) *IN GENERAL.*—The qualified independent contractor shall review initial determinations. Where an initial determination is made with respect to whether an item or service is reasonable and necessary for the diagnosis or treatment of illness or injury (under section 1862(a)(1)(A)), such review shall include consideration of the facts and circumstances of the initial determination by a panel of physicians or other appropriate health care professionals and any decisions with respect to the reconsideration shall be based on applicable information, including clinical experience (*including the medical records of the individual involved*) and medical, technical, and scientific evidence.

* * * * *

[(D) *LIMITATION ON INDIVIDUAL REVIEWING DETERMINATIONS.*—

[(i) *PHYSICIANS AND HEALTH CARE PROFESSIONAL.*—No physician or health care professional under the em-

ploy of a qualified independent contractor may review—

【(I) determinations regarding health care services furnished to a patient if the physician or health care professional was directly responsible for furnishing such services; or

【(II) determinations regarding health care services provided in or by an institution, organization, or agency, if the physician or any member of the family of the physician or health care professional has, directly or indirectly, a significant financial interest in such institution, organization, or agency.

【(ii) FAMILY DESCRIBED.—For purposes of this paragraph, the family of a physician or health care professional includes the spouse (other than a spouse who is legally separated from the physician or health care professional under a decree of divorce or separate maintenance), children (including stepchildren and legally adopted children), grandchildren, parents, and grandparents of the physician or health care professional.】

(D) QUALIFICATIONS FOR REVIEWERS.—*The requirements of subsection (g) shall be met (relating to qualifications of reviewing professionals).*

(E) EXPLANATION OF DECISION.—Any decision with respect to a reconsideration of a qualified independent contractor shall be in writing, *be written in a manner calculated to be understood by the beneficiary, and shall include (to the extent appropriate) and shall include a detailed explanation of the decision as well as a discussion of the pertinent facts and applicable regulations applied in making such decision, and a notification of the right to appeal such determination and instructions on how to initiate such appeal under this section* and in the case of a determination of whether an item or service is reasonable and necessary for the diagnosis or treatment of illness or injury (under section 1862(a)(1)(A)) an explanation of the medical and scientific rationale for the decision.

* * * * *

(I) DATA COLLECTION.—

(i) * * *

(ii) TYPE OF DATA COLLECTED.—Each qualified independent contractor shall keep accurate records of each decision made, consistent with standards established by the Secretary for such purpose. Such records shall be maintained in an electronic database in a manner that provides for identification of the following:

(I) * * *

* * * * *

(III) Situations suggesting the need for changes in national or local coverage 【policy】 *determination.*

(IV) Situations suggesting the need for changes in local **medical review policies** coverage determinations.

* * * * *

(J) HEARINGS BY THE SECRETARY.—The qualified independent contractor shall (i) prepare **such information as is required for an appeal** *the record for the appeal* of a decision of the contractor with respect to a reconsideration to the Secretary for a hearing, including as necessary, explanations of issues involved in the decision and relevant policies, and (ii) participate in such hearings as required by the Secretary.

* * * * *

(d) DEADLINES FOR HEARINGS BY THE SECRETARY; *NOTICE*.—

(1) * * *

* * * * *

(4) *NOTICE*.—*Notice of the decision of an administrative law judge shall be in writing in a manner calculated to be understood by the beneficiary and shall include—*

(A) *the specific reasons for the determination (including, to the extent appropriate, a summary of the clinical or scientific evidence used in making the determination);*

(B) *the procedures for obtaining additional information concerning the decision; and*

(C) *notification of the right to appeal the decision and instructions on how to initiate such an appeal under this section.*

* * * * *

(f) REVIEW OF COVERAGE DETERMINATIONS.—

(1) * * *

(2) LOCAL COVERAGE DETERMINATION.—

(A) IN GENERAL.—Review of any local coverage determination shall be subject to the following limitations:

(i) Upon the filing of a complaint by an aggrieved party, such a determination shall be reviewed by an administrative law judge **of the Social Security Administration**. The administrative law judge—

(I) * * *

* * * * *

(4) PENDING NATIONAL COVERAGE DETERMINATIONS.—

(A) IN GENERAL.—In the event the Secretary has not issued a national coverage or noncoverage determination with respect to a particular type or class of items or services, an aggrieved person (as described in paragraph (5)) may submit to the Secretary a request to make such a determination with respect to such items or services. By not later than the end of the 90-day period beginning on the date the Secretary receives such a request (notwithstanding the receipt by the Secretary of new evidence (if any) during such 90-day period), the Secretary shall take one of the following actions:

(i) * * *

* * * * *

(iv) Issue a notice that states that the Secretary has not completed a review of the request for a national coverage determination and that includes an identification of the remaining steps in the Secretary's review process and a deadline by which the Secretary will complete the review and take an action described in [subclause (I), (II), or (III)] *clause (i), (ii), or (iii)*.

(B) DEEMED ACTION BY THE SECRETARY.—In the case of an action described in [clause (i)(IV)] *subparagraph (A)(iv)*, if the Secretary fails to take an action referred to in such clause by the deadline specified by the Secretary under such clause, then the Secretary is deemed to have taken an action described in [clause (i)(III)] *subparagraph (A)(iii)* as of the deadline.

(C) EXPLANATION OF DETERMINATION.—When issuing a determination under [clause (i)] *subparagraph (A)*, the Secretary shall include an explanation of the basis for the determination. An action taken under [clause (i)] *subparagraph (A)* (other than [subclause (IV)] *clause (iv)*) is deemed to be a national coverage determination for purposes of review under [subparagraph (A)] *paragraph (1)(A)*.

* * * * *

(6) PROCESS FOR EXCEPTIONS TO NATIONAL COVERAGE DETERMINATIONS UNDER SPECIAL MEDICAL CIRCUMSTANCES.—

(A) ESTABLISHMENT OF PROCESS.—*The Secretary shall establish a process whereby an individual described in paragraph (5) may submit to the Secretary a request for a determination that a national coverage determination, which has the effect of denying coverage under this title for items and services for the treatment of a serious or life-threatening condition of the individual, should not apply to the individual due to the special medical circumstances of the individual that involve medical factors that were not considered during the national coverage determination decisionmaking procedure and make the application of the national coverage determination inappropriate for the individual's particular case. Such request shall be accompanied by supporting documentation and may be made before the receipt of the items or services involved.*

(B) USE OF PANEL.—*Under such process, the Secretary shall provide that—*

(i) the initial decision on the request is made by a panel described in subparagraph (C); or

(ii) the individual is provided the opportunity to appeal the initial decision on the request to such a panel.

(C) PANEL.—*A panel described in this subparagraph is a panel of physicians or other appropriate health care professionals in which each member of the panel meets the requirements of paragraphs (2) and (4) of subsection (g) (relating to independence and licensure and expertise).*

(D) *APPEAL.*—A decision on a request under this paragraph shall be subject to further review (after any appeal described in subparagraph (B)(ii)) by the Departmental Appeals Board and to judicial review, in the same manner as provided under subsection (b) with respect to review of a final decision of the Secretary.

(E) *EXPEDITION.*—The process under this paragraph shall provide for reasonable expedition for making decisions on requests when the need for expedition is certified by a physician.

(F) *EFFECT OF DECISION.*—If a request under this paragraph is approved for an individual with respect to a treatment, the national coverage determination shall not be applied by any medicare administrative contractor with respect to the treatment for that individual.

(G) *NOTICE.*—The Secretary shall provide, in an appropriate annual publication available to the public, a list of national coverage determinations and information on how to get more information with respect to such determinations, made in the previous year.

[(6)] (7) *PUBLICATION ON THE INTERNET OF DECISIONS OF HEARINGS OF THE SECRETARY.*—Each decision of a hearing by the Secretary with respect to a national coverage determination shall be made public, and the Secretary shall publish each decision on the Medicare Internet site of the Department of Health and Human Services. The Secretary shall remove from such decision any information that would identify any individual, provider of services, or supplier.

[(7)] (8) *ANNUAL REPORT ON NATIONAL COVERAGE DETERMINATIONS.*—

(A) * * *

* * * * *

[(8)] (9) *CONSTRUCTION.*—Nothing in this subsection shall be construed as permitting administrative or judicial review pursuant to this section insofar as such review is explicitly prohibited or restricted under another provision of law.

(g) *QUALIFICATIONS OF REVIEWERS.*—

(1) *IN GENERAL.*—In reviewing determinations under this section, a qualified independent contractor shall assure that—

(A) each individual conducting a review shall meet the qualifications of paragraph (2);

(B) compensation provided by the contractor to each such reviewer is consistent with paragraph (3); and

(C) in the case of a review by a panel described in subsection (c)(3)(B) composed of physicians or other health care professionals (each in this subsection referred to as a “reviewing professional”), each reviewing professional meets the qualifications described in paragraph (4) and, if the request for review indicates that the item or service involved was furnished (or ordered to be furnished) by a physician, each reviewing professional shall be a physician.

(2) *INDEPENDENCE.*—

(A) *IN GENERAL.*—Subject to subparagraph (B), each individual conducting a review in a case shall—

(i) not be a related party (as defined in paragraph (5));

(ii) not have a material familial, financial, or professional relationship with such a party in the case under review; and

(iii) not otherwise have a conflict of interest with such a party (as determined under regulations).

(B) *EXCEPTION.*—Nothing in subparagraph (A) shall be construed to—

(i) prohibit an individual, solely on the basis of affiliation with a fiscal intermediary, carrier, or other contractor, from serving as an reviewing professional if—

(I) a non-affiliated individual is not reasonably available;

(II) the affiliated individual is not involved in the provision of items or services in the case under review;

(III) the fact of such an affiliation is disclosed to the Secretary and the beneficiary (or authorized representative) and neither party objects; and

(IV) the affiliated individual is not an employee of the intermediary, carrier, or contractor and does not provide services exclusively or primarily to or on behalf of such intermediary, carrier, or contractor;

(ii) prohibit an individual who has staff privileges at the institution where the treatment involved takes place from serving as a reviewer merely on the basis of such affiliation if the affiliation is disclosed to the Secretary and the beneficiary (or authorized representative), and neither party objects; or

(iii) prohibit receipt of compensation by a reviewing professional from a contractor if the compensation is provided consistent with paragraph (3).

(3) *LIMITATIONS ON REVIEWER COMPENSATION.*—Compensation provided by a qualified independent contractor to a reviewer in connection with a review under this section shall—

(A) not exceed a reasonable level; and

(B) not be contingent on the decision rendered by the reviewer.

(4) *LICENSURE AND EXPERTISE.*—Each reviewing professional shall be a physician (allopathic or osteopathic) or health care professional who—

(A) is appropriately credentialed or licensed in 1 or more States to deliver health care services; and

(B) typically treats the condition, makes the diagnosis, or provides the type of treatment under review.

(5) *RELATED PARTY DEFINED.*—For purposes of this section, the term “related party” means, with respect to a case under this title involving an individual beneficiary, any of the following:

(A) The Secretary, the medicare administrative contractor involved, or any fiduciary, officer, director, or employee of

the Department of Health and Human Services, or of such contractor.

(B) The individual (or authorized representative).

(C) The health care professional that provides the items or services involved in the case.

(D) The institution at which the items or services (or treatment) involved in the case are provided.

(E) The manufacturer of any drug or other item that is included in the items or services involved in the case.

(F) Any other party determined under any regulations to have a substantial interest in the case involved.

(h) **PRIOR DETERMINATION PROCESS FOR CERTAIN ITEMS AND SERVICES.**—

(1) **ESTABLISHMENT OF PROCESS.**—

(A) **IN GENERAL.**—With respect to a medicare administrative contractor that has a contract under section 1874A that provides for making payments under this title with respect to items and services, the Secretary shall establish a prior determination process that meets the requirements of this subsection and that shall be applied by such contractor in the case of eligible requesters.

(B) **ELIGIBLE REQUESTER.**—For purposes of this subsection, the term “eligible requester” means—

(i) a physician, but only in the case of items and services that may be furnished (or ordered to be furnished) by the physician; and

(ii) an individual entitled to benefits under this title, but only with respect to an item or service for which the individual receives an advance beneficiary notice from the provider or supplier of the item or service under section 1879 that payment may not be made (or may no longer be made) for the item or service under this title.

(2) **ESTABLISHING ELIGIBLE CATEGORIES.**—The Secretary shall establish by regulation limits on the categories of items and services for which a prior determination of coverage may be requested under this subsection. In establishing such limits, the Secretary may consider the dollar amount involved with respect to the item or service, administrative costs and burdens, and other relevant factors.

(3) **REQUEST FOR PRIOR DETERMINATION.**—

(A) **IN GENERAL.**—Subject to paragraph (2), under the process established under this subsection any eligible requester may submit to the contractor a request for a determination, before the furnishing (or ordering the furnishing) of the item or service involved as to whether the item or service is covered under this title consistent with the applicable requirements of section 1862(a) (relating to medical necessity, etc.).

(B) **ACCOMPANYING DOCUMENTATION.**—The request shall be accompanied by a description of the item or service, its billing code (as appropriate), supporting documentation relating to the medical necessity for the item or service, and any other appropriate documentation that the Secretary may require. In the case of a request submitted by an eligi-

ble requester that is described in paragraph (1)(B)(ii), the request shall also be accompanied by a copy of the advance beneficiary notice involved.

(4) *RESPONSE TO REQUEST.*—

(A) *IN GENERAL.*—Under such process, the contractor shall provide the eligible requester with written notice of a determination as to whether—

- (i) the item or service is so covered;
- (ii) the item or service is not so covered; or
- (iii) the contractor lacks sufficient information to make a coverage determination.

In the case of a request in which an eligible requester is not the beneficiary described in paragraph (1)(B)(i), the process shall provide that the beneficiary involved shall be informed of any determination described in clause (ii) (relating to a determination of non-coverage).

(B) *DEADLINE TO RESPOND.*—Such notice shall be provided within the same time period as the time period applicable to the contractor providing notice of initial determinations on a claim for benefits under subsection (a)(2)(A).

(5) *EFFECT OF DETERMINATIONS.*—

(A) *BINDING NATURE OF POSITIVE DETERMINATION.*—If the contractor makes the determination described in paragraph (4)(A)(i), such determination shall be binding on the contractor in the absence of fraud or evidence of misrepresentation of facts presented to the contractor.

(B) *RIGHT TO REDETERMINATION IN CASE OF A DENIAL.*—

(i) *IN GENERAL.*—If the contractor makes the determination described in paragraph (4)(A)(ii)—

(I) the eligible requester has the right to a redetermination by the contractor on the determination that the item or service is not so covered; and

(II) the contractor shall include in notice under paragraph (4)(A) a brief explanation of the basis for the determination and the right to such a redetermination.

(ii) *DEADLINE FOR REDETERMINATIONS.*—The contractor shall complete and provide notice of such redetermination within the same time period as the time period applicable to the contractor providing notice of redeterminations relating to a claim for benefits under subsection (a)(3)(C)(ii).

(C) *DESCRIPTION OF ADDITIONAL INFORMATION REQUIRED.*—If the contractor makes the determination described in paragraph (4)(A)(iii), the contractor shall include in the notice under paragraph (4)(A) a description of the additional information required to make the coverage determination.

(6) *LIMITATION ON FURTHER REVIEW.*—

(A) *IN GENERAL.*—Contractor determinations described in paragraph (4)(A)(ii) or (4)(A)(iii) (and redeterminations made under paragraph (5)(B)), relating to pre-service claims are not subject to further administrative appeal or judicial review under this section or otherwise.

(B) CONSTRUCTION.—Nothing in this subsection shall be construed as affecting the right of an individual, after receiving items or services for which the contractor has made a determination described in paragraph (4)(A)(ii), from submitting a claim for such item or service or from obtaining administrative or judicial review respecting such claim under the other applicable provisions of this section.

OVERPAYMENT ON BEHALF OF INDIVIDUALS AND SETTLEMENT OF CLAIMS FOR BENEFITS ON BEHALF OF DECEASED INDIVIDUALS

SEC. 1870. (a) * * *

* * * * *

(h) Notwithstanding subsection (f) or any other provision of law, the Secretary shall permit a provider of services, physician, practitioner, facility, or supplier to appeal any determination of the Secretary under this title relating to services rendered under this title to an individual who subsequently dies, if there is no other party available to appeal such determination, so long as the estate of the individual, and the individual's family and heirs, are not liable for paying for the item or service and are not liable for any increased coinsurance or deductible amounts resulting from any decision increasing the reimbursement amount for the provider of services, physician, practitioner, facility, or supplier.

REGULATIONS

SEC. 1871. (a)(1) * * *

* * * * *

(3)(A) The Secretary, in consultation with the Director of the Office of Management and Budget, shall establish a regular timeline for the publication of final regulations based on the previous publication of a proposed regulation or an interim final regulation.

(B) With respect to publication of final regulations based on the previous publication of a proposed regulation, such timeline may vary among different regulations based on differences in the complexity of the regulation, the number and scope of comments received, and other relevant factors.

(C)(i) With respect to the publication of final regulations based on the previous publication of an interim final regulation—

(I) subject to clause (ii), the Secretary shall publish the final regulation within the 12-month period that begins on the date of publication of the interim final regulation;

(II) if a final regulation is not published by the deadline established under this subparagraph, the interim final regulation shall not continue in effect unless the Secretary publishes a notice described in clause (ii) by such deadline; and

(III) the final regulation shall include responses to comments submitted in response to the interim final regulation.

(ii) If the Secretary determines before the deadline otherwise established in this subparagraph that there is good cause, specified in a notice published before such deadline, for delaying the deadline otherwise applicable under this subparagraph, the deadline otherwise established under this subparagraph shall be extended for such period as the Secretary specifies in such notice.

(4) Insofar as a final regulation (other than an interim final regulation) includes a provision that is not a logical outgrowth of the relevant notice of proposed rulemaking relating to such regulation, that provision shall be treated as a proposed regulation and shall not take effect until there is the further opportunity for public comment and a publication of the provision again as a final regulation.

* * * * *

(d)(1) Subject to paragraph (2), the Secretary shall issue final (including interim final) regulations to carry out this title only on one business day of every month.

(2) The Secretary may issue a final regulation described in paragraph (1) on any other day than the day described in paragraph (1) if the Secretary—

(A) finds that issuance of such regulation on another day is necessary to comply with requirements under law; or

(B) finds that with respect to that regulation the limitation of issuance on the date described in paragraph (1) is contrary to the public interest.

If the Secretary makes a finding under this paragraph, the Secretary shall include such finding, and brief statement of the reasons for such finding, in the issuance of such regulation.

(e)(1)(A) A substantive change in regulations, manual instructions, interpretative rules, statements of policy, or guidelines of general applicability under this title shall not be applied (by extrapolation or otherwise) retroactively to items and services furnished before the effective date of the change, unless the Secretary determines that—

(i) such retroactive application is necessary to comply with statutory requirements; or

(ii) failure to apply the change retroactively would be contrary to the public interest.

(B) A compliance action may be made against a provider of services, physician, practitioner, facility, or supplier with respect to non-compliance with a substantive change referred to in subparagraph (A) only for items and services furnished on or after the effective date of the change.

(C)(i) Except as provided in clause (ii), a substantive change referred to in subparagraph (A) may not take effect before the end of the 30-day period that begins on the date that the Secretary has issued or published, as the case may be, the substantive change.

(ii) The Secretary may provide for such a substantive change to take effect on a date that precedes the end of the 30-day period under clause (i) if the Secretary finds that waiver of such 30-day period is necessary to comply with statutory requirements or that the application of such 30-day period is contrary to the public interest. If the Secretary provides for an earlier effective date pursuant to this clause, the Secretary shall include in the issuance or publication of the substantive change a finding described in the first sentence, and a brief statement of the reasons for such finding.

(2) If—

(A) a provider of services, physician, practitioner, facility, or supplier follows written guidance (which may have been transmitted electronically) provided—

(i) by the Secretary; or

(ii) by a medicare contractor (as defined in section 1889(f) and whether in the form of a written response to a written inquiry under section 1874A(g)(1) or otherwise) acting within the scope of the contractor's contract authority, in response to a written inquiry with respect to the furnishing of an item or service or the submission of a claim for benefits for such an item or service;

(B) the Secretary determines that—

(i) the provider of services, physician, practitioner, facility, or supplier has accurately presented the circumstances relating to such item, service, and claim to the Secretary or the contractor in the written guidance; and

(ii) there is no indication of fraud or abuse committed by the provider of services, physician, practitioner, facility, or supplier against the program under this title; and

(C) the guidance was in error;

the provider of services, physician, practitioner, facility, or supplier shall not be subject to any penalty or interest (relating to an overpayment, if any) under this title (or the provisions of title XI insofar as they relate to this title) relating to the provision of such item or service or such claim if the provider of services, physician, practitioner, facility, or supplier reasonably relied on such guidance. In applying this paragraph with respect to guidance in the form of general responses to frequently asked questions, the Secretary retains authority to determine the extent to which such general responses apply to the particular circumstances of individual claims. Nothing in this paragraph shall be construed as affecting the application of section 1870(c) (relating to no adjustment in the cases of certain overpayments).

(f)(1) Not later than 2 years after the date of the enactment of this subsection, and every 2 years thereafter, the Secretary shall submit to Congress a report with respect to the administration of this title and areas of inconsistency or conflict among the various provisions under law and regulation.

(2) In preparing a report under paragraph (1), the Secretary shall collect—

(A) information from beneficiaries, providers of services, physicians, practitioners, facilities, and suppliers, and from the individual under section 404 of the Medicare Regulatory, Appeals, Contracting, and Education Reform Act of 2001 with respect to such areas of inconsistency and conflict; and

(B) information from medicare contractors that tracks the nature of written and telephone inquiries.

(3) A report under paragraph (1) shall include a description of efforts by the Secretary to reduce such inconsistency or conflicts, and recommendations for legislation or administrative action that the Secretary determines appropriate to further reduce such inconsistency or conflicts.

(g)(1)(A) The Secretary shall establish by regulation procedures under which there are deadlines for actions on applications for enrollment (and, if applicable, renewal of enrollment).

(B) The Secretary shall monitor the performance of medicare administrative contractors in meeting the deadlines established under subparagraph (A).

(2) *The Secretary shall consult with providers of services, physicians, practitioners, facilities, and suppliers before making changes in the provider enrollment forms required of such providers, physicians, practitioners, facilities, and suppliers to be eligible to submit claims for which payment may be made under this title.*

* * * * *

CONTRACTS WITH MEDICARE ADMINISTRATIVE CONTRACTORS

SEC. 1874A. (a) *AUTHORITY.*—

(1) *AUTHORITY TO ENTER INTO CONTRACTS.*—*The Secretary may enter into contracts with any eligible entity to serve as a medicare administrative contractor with respect to the performance of any or all of the functions described in paragraph (4) or parts of those functions (or, to the extent provided in a contract, to secure performance thereof by other entities).*

(2) *ELIGIBILITY OF ENTITIES.*—*An entity is eligible to enter into a contract with respect to the performance of a particular function or activity described in paragraph (4) only if—*

(A) *the entity has demonstrated capability to carry out such function;*

(B) *the entity complies with such conflict of interest standards as are generally applicable to Federal acquisition and procurement;*

(C) *the entity has sufficient assets to financially support the performance of such function; and*

(D) *the entity meets such other requirements as the Secretary may impose.*

(3) *MEDICARE ADMINISTRATIVE CONTRACTOR DEFINED.*—*For purposes of this title and title XI—*

(A) *IN GENERAL.*—*The term “medicare administrative contractor” means an agency, organization, or other person with a contract under this section.*

(B) *APPROPRIATE MEDICARE ADMINISTRATIVE CONTRACTOR.*—*With respect to the performance of a particular function or activity in relation to an individual entitled to benefits under part A or enrolled under part B, or both, a specific provider of services, physician, practitioner, facility, or supplier (or class of such providers of services, physicians, practitioners, facilities, or suppliers), the “appropriate” medicare administrative contractor is the medicare administrative contractor that has a contract under this section with respect to the performance of that function or activity in relation to that individual, provider of services, physician, practitioner, facility, or supplier or class of provider of services, physician, practitioner, facility, or supplier.*

(4) *FUNCTIONS DESCRIBED.*—*The functions referred to in paragraphs (1) and (2) are payment functions, provider services functions, and beneficiary services functions as follows:*

(A) *DETERMINATION OF PAYMENT AMOUNTS.*—*Determining (subject to the provisions of section 1878 and to such review by the Secretary as may be provided for by the contracts) the amount of the payments required pursuant to*

this title to be made to providers of services, physicians, practitioners, facilities, suppliers, and individuals.

(B) MAKING PAYMENTS.—Making payments described in subparagraph (A) (including receipt, disbursement, and accounting for funds in making such payments).

(C) BENEFICIARY EDUCATION AND ASSISTANCE.—Serving as a center for, and communicating to individuals entitled to benefits under part A or enrolled under part B, or both, with respect to education and outreach for those individuals, and assistance with specific issues, concerns or problems of those individuals.

(D) PROVIDER CONSULTATIVE SERVICES.—Providing consultative services to institutions, agencies, and other persons to enable them to establish and maintain fiscal records necessary for purposes of this title and otherwise to qualify as providers of services, physicians, practitioners, facilities, or suppliers.

(E) COMMUNICATION WITH PROVIDERS.—Serving as a center for, and communicating to providers of services, physicians, practitioners, facilities, and suppliers, any information or instructions furnished to the medicare administrative contractor by the Secretary, and serving as a channel of communication from such providers, physicians, practitioners, facilities, and suppliers to the Secretary.

(F) PROVIDER EDUCATION AND TECHNICAL ASSISTANCE.—Performing the functions described in subsections (e) and (f), relating to education, training, and technical assistance to providers of services, physicians, practitioners, facilities, and suppliers.

(G) ADDITIONAL FUNCTIONS.—Performing such other functions as are necessary to carry out the purposes of this title.

(5) RELATIONSHIP TO MIP CONTRACTS.—

(A) NONDUPLICATION OF DUTIES.—In entering into contracts under this section, the Secretary shall assure that functions of medicare administrative contractors in carrying out activities under parts A and B do not duplicate functions carried out under the Medicare Integrity Program under section 1893. The previous sentence shall not apply with respect to the activity described in section 1893(b)(5) (relating to prior authorization of certain items of durable medical equipment under section 1834(a)(15)).

(B) CONSTRUCTION.—An entity shall not be treated as a medicare administrative contractor merely by reason of having entered into a contract with the Secretary under section 1893.

(6) APPLICATION OF FEDERAL ACQUISITION REGULATION.—*Except to the extent inconsistent with a specific requirement of this title, the Federal Acquisition Regulation applies to contracts under this title.*

(b) CONTRACTING REQUIREMENTS.—

(1) USE OF COMPETITIVE PROCEDURES.—

(A) IN GENERAL.—Except as provided in laws with general applicability to Federal acquisition and procurement or in subparagraph (B), the Secretary shall use competitive

procedures when entering into contracts with medicare administrative contractors under this section.

(B) *RENEWAL OF CONTRACTS.*—*The Secretary may renew a contract with a medicare administrative contractor under this section from term to term without regard to section 5 of title 41, United States Code, or any other provision of law requiring competition, if the medicare administrative contractor has met or exceeded the performance requirements applicable with respect to the contract and contractor, except that the Secretary shall provide for the application of competitive procedures under such a contract not less frequently than once every five years.*

(C) *TRANSFER OF FUNCTIONS.*—*The Secretary may transfer functions among medicare administrative contractors without regard to any provision of law requiring competition. The Secretary shall ensure that performance quality is considered in such transfers. The Secretary shall provide notice (whether in the Federal Register or otherwise) of any such transfer (including a description of the functions so transferred and contact information for the contractors involved) to providers of services, physicians, practitioners, facilities, and suppliers affected by the transfer.*

(D) *INCENTIVES FOR QUALITY.*—*The Secretary shall provide incentives for medicare administrative contractors to provide quality service and to promote efficiency.*

(2) *COMPLIANCE WITH REQUIREMENTS.*—*No contract under this section shall be entered into with any medicare administrative contractor unless the Secretary finds that such medicare administrative contractor will perform its obligations under the contract efficiently and effectively and will meet such requirements as to financial responsibility, legal authority, and other matters as the Secretary finds pertinent.*

(3) *PERFORMANCE REQUIREMENTS.*—

(A) *DEVELOPMENT OF SPECIFIC PERFORMANCE REQUIREMENTS.*—*The Secretary shall develop contract performance requirements to carry out the specific requirements applicable under this title to a function described in subsection (a)(4) and shall develop standards for measuring the extent to which a contractor has met such requirements. The Secretary shall publish in the Federal Register such performance requirements and measurement standards.*

(B) *CONSIDERATIONS.*—*The Secretary may include as one of the standards satisfaction level as measured by provider and beneficiary surveys.*

(C) *INCLUSION IN CONTRACTS.*—*All contractor performance requirements shall be set forth in the contract between the Secretary and the appropriate medicare administrative contractor. Such performance requirements—*

(i) shall reflect the performance requirements published under subparagraph (A), but may include additional performance requirements;

(ii) shall be used for evaluating contractor performance under the contract; and

(iii) shall be consistent with the written statement of work provided under the contract.

(4) *INFORMATION REQUIREMENTS.*—The Secretary shall not enter into a contract with a medicare administrative contractor under this section unless the contractor agrees—

(A) to furnish to the Secretary such timely information and reports as the Secretary may find necessary in performing his functions under this title; and

(B) to maintain such records and afford such access thereto as the Secretary finds necessary to assure the correctness and verification of the information and reports under subparagraph (A) and otherwise to carry out the purposes of this title.

(5) *SURETY BOND.*—A contract with a medicare administrative contractor under this section may require the medicare administrative contractor, and any of its officers or employees certifying payments or disbursing funds pursuant to the contract, or otherwise participating in carrying out the contract, to give surety bond to the United States in such amount as the Secretary may deem appropriate.

(c) *TERMS AND CONDITIONS.*—

(1) *IN GENERAL.*—A contract with any medicare administrative contractor under this section may contain such terms and conditions as the Secretary finds necessary or appropriate and may provide for advances of funds to the medicare administrative contractor for the making of payments by it under subsection (a)(4)(B).

(2) *PROHIBITION ON MANDATES FOR CERTAIN DATA COLLECTION.*—The Secretary may not require, as a condition of entering into, or renewing, a contract under this section, that the medicare administrative contractor match data obtained other than in its activities under this title with data used in the administration of this title for purposes of identifying situations in which the provisions of section 1862(b) may apply.

(d) *LIMITATION ON LIABILITY OF MEDICARE ADMINISTRATIVE CONTRACTORS AND CERTAIN OFFICERS.*—

(1) *CERTIFYING OFFICER.*—No individual designated pursuant to a contract under this section as a certifying officer shall, in the absence of gross negligence or intent to defraud the United States, be liable with respect to any payments certified by the individual under this section.

(2) *DISBURSING OFFICER.*—No disbursing officer shall, in the absence of gross negligence or intent to defraud the United States, be liable with respect to any payment by such officer under this section if it was based upon an authorization (which meets the applicable requirements for such internal controls established by the Comptroller General) of a certifying officer designated as provided in paragraph (1) of this subsection.

(3) *LIABILITY OF MEDICARE ADMINISTRATIVE CONTRACTOR.*—No medicare administrative contractor shall be liable to the United States for a payment by a certifying or disbursing officer unless in connection with such payment or in the supervision of or selection of such officer the medicare administrative contractor acted with gross negligence.

(4) *LIMITATION ON CIVIL LIABILITY.*—

(A) *IN GENERAL.*—No medicare administrative contractor having a contract with the Secretary under this section,

and no person employed by, or having a fiduciary relationship with, any such medicare administrative contractor or who furnishes professional services to such medicare administrative contractor, shall by reason of the performance of any duty, function, or activity required or authorized pursuant to this section or to a valid contract entered into under this section, be held civilly liable under any law of the United States or of any State (or political subdivision thereof) provided due care was exercised in the performance of such duty, function, or activity.

(B) REIMBURSEMENT OF CERTAIN EXPENSES.—The Secretary shall make payment to a medicare administrative contractor under contract with the Secretary pursuant to this section, or to any member or employee thereof, or to any person who furnishes legal counsel or services to such medicare administrative contractor, in an amount equal to the reasonable amount of the expenses incurred, as determined by the Secretary, in connection with the defense of any civil suit, action, or proceeding brought against such medicare administrative contractor or person related to the performance of any duty, function, or activity under such contract, provided due care was exercised in the performance of such duty, function, or activity.

(e) REQUIREMENTS FOR INFORMATION SECURITY.—

(1) DEVELOPMENT OF INFORMATION SECURITY PROGRAM.—A medicare administrative contractor that performs the functions referred to in subparagraphs (A) and (B) of subsection (a)(4) (relating to determining and making payments) shall implement a contractor-wide information security program to provide information security for the operation and assets of the contractor with respect to such functions under this title. An information security program under this paragraph shall meet the requirements for information security programs imposed on Federal agencies under section 3534(b)(2) of title 44, United States Code (other than requirements under subparagraphs (B)(ii), (F)(iii), and (F)(iv) of such section).

(2) INDEPENDENT AUDITS.—

(A) PERFORMANCE OF ANNUAL EVALUATIONS.—Each year a medicare administrative contractor that performs the functions referred to in subparagraphs (A) and (B) of subsection (a)(4) (relating to determining and making payments) shall undergo an evaluation of the information security of the contractor with respect to such functions under this title. The evaluation shall—

(i) be performed by an entity that meets such requirements for independence as the Inspector General of the Department of Health and Human Services may establish; and

(ii) test the effectiveness of information security control techniques for an appropriate subset of the contractor's information systems (as defined in section 3502(8) of title 44, United States Code) relating to such functions under this title and an assessment of compliance with the requirements of this subsection and related in-

formation security policies, procedures, standards and guidelines.

(B) DEADLINE FOR INITIAL EVALUATION.—

(i) **NEW CONTRACTORS.**—*In the case of a medicare administrative contractor covered by this subsection that has not previously performed the functions referred to in subparagraphs (A) and (B) of subsection (a)(4) (relating to determining and making payments) as a fiscal intermediary or carrier under section 1816 or 1842, the first independent evaluation conducted pursuant subparagraph (A) shall be completed prior to commencing such functions.*

(ii) **OTHER CONTRACTORS.**—*In the case of a medicare administrative contractor covered by this subsection that is not described in clause (i), the first independent evaluation conducted pursuant subparagraph (A) shall be completed within 1 year after the date the contractor commences functions referred to in clause (i) under this section.*

(C) REPORTS ON EVALUATIONS.—

(i) **TO THE INSPECTOR GENERAL.**—*The results of independent evaluations under subparagraph (A) shall be submitted promptly to the Inspector General of the Department of Health and Human Services.*

(ii) **TO CONGRESS.**—*The Inspector General of Department of Health and Human Services shall submit to Congress annual reports on the results of such evaluations.*

(f) INCENTIVES TO IMPROVE CONTRACTOR PERFORMANCE IN PROVIDER EDUCATION AND OUTREACH.—*In order to give medicare administrative contractors an incentive to implement effective education and outreach programs for providers of services, physicians, practitioners, facilities, and suppliers, the Secretary shall implement, a methodology to measure the specific claims payment error rates of such contractors in the processing or reviewing of medicare claims.*

(g) COMMUNICATIONS WITH BENEFICIARIES, PROVIDERS OF SERVICES, PHYSICIANS, PRACTITIONERS, FACILITIES, AND SUPPLIERS.—

(1) COMMUNICATION STRATEGY.—*The Secretary shall develop a strategy for communications with beneficiaries and with providers of services, physicians, practitioners, facilities, and suppliers under this title.*

(2) RESPONSE TO WRITTEN INQUIRIES.—*Each medicare administrative contractor shall, for those providers of services, physicians, practitioners, facilities, and suppliers which submit claims to the contractor for claims processing and for those beneficiaries with respect to which claims are submitted for claims processing, provide general written responses (which may be through electronic transmission) in a clear, concise, and accurate manner to inquiries by beneficiaries, providers of services, physicians, practitioners, facilities, and suppliers concerning the programs under this title within 45 business days of the date of receipt of such inquiries.*

(3) RESPONSE TO TOLL-FREE LINES.—*Each medicare administrative contractor shall, for those providers of services, physi-*

cians, practitioners, facilities, and suppliers which submit claims to the contractor for claims processing and for those beneficiaries with respect to which claims are submitted for claims processing, maintain a toll-free telephone number at which beneficiaries, providers, physicians, practitioners, facilities, and suppliers may obtain information regarding billing, coding, claims, coverage, and other appropriate information under this title.

(4) MONITORING OF CONTRACTOR RESPONSES.—

(A) *IN GENERAL.*—Each medicare administrative contractor shall, consistent with standards developed by the Secretary under subparagraph (B)—

(i) maintain a system for identifying who provides the information referred to in paragraphs (2) and (3); and

(ii) monitor the accuracy, consistency, and timeliness of the information so provided.

(B) *DEVELOPMENT OF STANDARDS.*—

(i) *IN GENERAL.*—The Secretary shall establish (and publish in the Federal Register) standards to monitor the accuracy, consistency, and timeliness of the information provided in response to written and telephone inquiries under this subsection. Such standards shall be consistent with the performance requirements established under subsection (b)(3).

(ii) *EVALUATION.*—In conducting evaluations of individual medicare administrative contractors, the Secretary shall take into account the results of the monitoring conducted under subparagraph (A) taking into account as performance requirements the standards established under clause (i).

(C) *DIRECT MONITORING.*—Nothing in this paragraph shall be construed as preventing the Secretary from directly monitoring the accuracy, consistency, and timeliness of the information so provided.

(h) *CONDUCT OF PREPAYMENT REVIEW.*—

(1) *STANDARDIZATION OF RANDOM PREPAYMENT REVIEW.*—If a medicare administrative contractor conducts a random prepayment review, the contractor may only conduct such review in accordance with a standard protocol for random prepayment audits developed by the Secretary.

(2) *LIMITATIONS ON INITIATION OF NON-RANDOM PREPAYMENT REVIEW.*—A medicare administrative contractor may not initiate non-random prepayment review of a provider of services, physician, practitioner, facility, or supplier based on the initial identification by that provider of services, physician, practitioner, facility, or supplier of an improper billing practice unless there is a likelihood of sustained or high level of payment error (as defined by the Secretary).

(3) *TERMINATION OF NON-RANDOM PREPAYMENT REVIEW.*—The Secretary shall issue regulations relating to the termination, including termination dates, of non-random prepayment review. Such regulations may vary such a termination date based upon the differences in the circumstances triggering prepayment review.

(4) *CONSTRUCTION.*—Nothing in this subsection shall be construed as preventing the denial of payments for claims actually reviewed under a random prepayment review. In the case of a provider of services, physician, practitioner, facility, or supplier with respect to which amounts were previously overpaid, nothing in this subsection shall be construed as limiting the ability of a medicare administrative contractor to request the periodic production of records or supporting documentation for a limited sample of submitted claims to ensure that the previous practice is not continuing.

(5) *RANDOM PREPAYMENT REVIEW DEFINED.*—For purposes of this subsection, the term “random prepayment review” means a demand for the production of records or documentation absent cause with respect to a claim.

(i) *RECOVERY OF OVERPAYMENTS.*—

(1) *USE OF REPAYMENT PLANS.*—

(A) *IN GENERAL.*—If the repayment, within the period otherwise permitted by a provider of services, physician, practitioner, facility, or supplier, of an overpayment under this title meets the standards developed under subparagraph (B), subject to subparagraph (C), and the provider, physician, practitioner, facility, or supplier requests the Secretary to enter into a repayment plan with respect to such overpayment, the Secretary shall enter into a plan with the provider, physician, practitioner, facility, or supplier for the offset or repayment (at the election of the provider, physician, practitioner, facility, or supplier) of such overpayment over a period of at least one year, but not longer than 3 years. Interest shall accrue on the balance through the period of repayment. The repayment plan shall meet terms and conditions determined to be appropriate by the Secretary.

(B) *DEVELOPMENT OF STANDARDS.*—The Secretary shall develop standards for the recovery of overpayments. Such standards shall—

(i) include a requirement that the Secretary take into account (and weigh in favor of the use of a repayment plan) the reliance (as described in section 1871(e)(2)) by a provider of services, physician, practitioner, facility, and supplier on guidance when determining whether a repayment plan should be offered; and

(ii) provide for consideration of the financial hardship imposed on a provider of services, physician, practitioner, facility, or supplier in considering such a repayment plan.

In developing standards with regard to financial hardship with respect to a provider of services, physician, practitioner, facility, or supplier, the Secretary shall take into account the amount of the proposed recovery as a proportion of payments made to that provider, physician, practitioner, facility, or supplier.

(C) *EXCEPTIONS.*—Subparagraph (A) shall not apply if—

(i) the Secretary has reason to suspect that the provider of services, physician, practitioner, facility, or supplier may file for bankruptcy or otherwise cease to

do business or discontinue participation in the program under this title; or

(ii) there is an indication of fraud or abuse committed against the program.

(D) IMMEDIATE COLLECTION IF VIOLATION OF REPAYMENT PLAN.—If a provider of services, physician, practitioner, facility, or supplier fails to make a payment in accordance with a repayment plan under this paragraph, the Secretary may immediately seek to offset or otherwise recover the total balance outstanding (including applicable interest) under the repayment plan.

(E) RELATION TO NO FAULT PROVISION.—Nothing in this paragraph shall be construed as affecting the application of section 1870(c) (relating to no adjustment in the cases of certain overpayments).

(2) LIMITATION ON RECOUPMENT.—

(A) NO RECOUPMENT UNTIL RECONSIDERATION EXERCISED.—In the case of a provider of services, physician, practitioner, facility, or supplier that is determined to have received an overpayment under this title and that seeks a reconsideration by a qualified independent contractor on such determination under section 1869(b)(1), the Secretary may not take any action (or authorize any other person, including any medicare contractor, as defined in subparagraph (C)) to recoup the overpayment until the date the decision on the reconsideration has been rendered. If the provisions of section 1869(b)(1) (providing for such a reconsideration by a qualified independent contractor) are not in effect, in applying the previous sentence any reference to such a reconsideration shall be treated as a reference to a redetermination by the fiscal intermediary or carrier involved.

(B) PAYMENT OF INTEREST.—

(i) RETURN OF RECOUPED AMOUNT WITH INTEREST IN CASE OF REVERSAL.—Insofar as such determination on appeal against the provider of services, physician, practitioner, facility, or supplier is later reversed, the Secretary shall provide for repayment of the amount recouped plus interest for the period in which the amount was recouped.

(ii) INTEREST IN CASE OF AFFIRMATION.—Insofar as the determination on such appeal is against the provider of services, physician, practitioner, facility, or supplier, interest on the overpayment shall accrue on and after the date of the original notice of overpayment.

(iii) RATE OF INTEREST.—The rate of interest under this subparagraph shall be the rate otherwise applicable under this title in the case of overpayments.

(C) MEDICARE CONTRACTOR DEFINED.—For purposes of this subsection, the term “medicare contractor” has the meaning given such term in section 1889(f).

(3) PAYMENT AUDITS.—

(A) WRITTEN NOTICE FOR POST-PAYMENT AUDITS.—Subject to subparagraph (C), if a medicare contractor decides to conduct a post-payment audit of a provider of services,

physician, practitioner, facility, or supplier under this title, the contractor shall provide the provider of services, physician, practitioner, facility, or supplier with written notice (which may be in electronic form) of the intent to conduct such an audit.

(B) *EXPLANATION OF FINDINGS FOR ALL AUDITS.*—Subject to subparagraph (C), if a medicare contractor audits a provider of services, physician, practitioner, facility, or supplier under this title, the contractor shall—

(i) give the provider of services, physician, practitioner, facility, or supplier a full review and explanation of the findings of the audit in a manner that is understandable to the provider of services, physician, practitioner, facility, or supplier and permits the development of an appropriate corrective action plan;

(ii) inform the provider of services, physician, practitioner, facility, or supplier of the appeal rights under this title as well as consent settlement options (which are at the discretion of the Secretary);

(iii) give the provider of services, physician, practitioner, facility, or supplier an opportunity to provide additional information to the contractor; and

(iv) take into account information provided, on a timely basis, by the provider of services, physician, practitioner, facility, or supplier under clause (iii).

(C) *EXCEPTION.*—Subparagraphs (A) and (B) shall not apply if the provision of notice or findings would compromise pending law enforcement activities, whether civil or criminal, or reveal findings of law enforcement-related audits.

(4) *NOTICE OF OVER-UTILIZATION OF CODES.*—The Secretary shall establish, in consultation with organizations representing the classes of providers of services, physicians, practitioners, facilities, and suppliers, a process under which the Secretary provides for notice to classes of providers of services, physicians, practitioners, facilities, and suppliers served by a medicare contractor in cases in which the contractor has identified that particular billing codes may be overutilized by that class of providers of services, physicians, practitioners, facilities, or suppliers under the programs under this title (or provisions of title XI insofar as they relate to such programs).

(5) *STANDARD METHODOLOGY FOR PROBE SAMPLING.*—The Secretary shall establish a standard methodology for medicare contractors to use in selecting a sample of claims for review in the case of an abnormal billing pattern.

(6) *CONSENT SETTLEMENT REFORMS.*—

(A) *IN GENERAL.*—The Secretary may use a consent settlement (as defined in subparagraph (D)) to settle a projected overpayment.

(B) *OPPORTUNITY TO SUBMIT ADDITIONAL INFORMATION BEFORE CONSENT SETTLEMENT OFFER.*—Before offering a provider of services, physician, practitioner, facility, or supplier a consent settlement, the Secretary shall—

(i) communicate to the provider of services, physician, practitioner, facility, or supplier in a non-threatening manner—

(I) that, based on a review of the medical records requested by the Secretary, a preliminary evaluation of those records indicates that there would be an overpayment;

(II) the nature of the problems identified in such evaluation; and

(III) the steps that the provider of services, physician, practitioner, facility, or supplier should take to address the problems; and

(ii) provide for a 45-day period during which the provider of services, physician, practitioner, facility, or supplier may furnish additional information concerning the medical records for the claims that had been reviewed.

(C) *CONSENT SETTLEMENT OFFER.*—The Secretary shall review any additional information furnished by the provider of services, physician, practitioner, facility, or supplier under subparagraph (B)(ii). Taking into consideration such information, the Secretary shall determine if there still appears to be an overpayment. If so, the Secretary—

(i) shall provide notice of such determination to the provider of services, physician, practitioner, facility, or supplier, including an explanation of the reason for such determination; and

(ii) in order to resolve the overpayment, may offer the provider of services, physician, practitioner, facility, or supplier—

(I) the opportunity for a statistically valid random sample; or

(II) a consent settlement.

The opportunity provided under clause (ii)(I) does not waive any appeal rights with respect to the alleged overpayment involved.

(D) *CONSENT SETTLEMENT DEFINED.*—For purposes of this paragraph, the term “consent settlement” means an agreement between the Secretary and a provider of services, physician, practitioner, facility, or supplier whereby both parties agree to settle a projected overpayment based on less than a statistically valid sample of claims and the provider of services, physician, practitioner, facility, or supplier agrees not to appeal the claims involved.

(7) *LIMITATION ON USE OF EXTRAPOLATION.*—A medicare contractor may not use extrapolation to determine overpayment amounts to be recovered by recoupment, offset, or otherwise unless—

(A) there is a sustained or high level of payment error (as defined by the Secretary by regulation); or

(B) documented educational intervention has failed to correct the payment error (as determined by the Secretary).

* * * * *

PROVIDER EDUCATION AND TECHNICAL ASSISTANCE

SEC. 1889. (a) COORDINATION OF EDUCATION FUNDING.—The Secretary shall coordinate the educational activities provided through medicare contractors (as defined in subsection (f), including under section 1893) in order to maximize the effectiveness of Federal education efforts for providers of services, physicians, practitioners, facilities, and suppliers.

(b) INTERNET SITES; FAQs.—The Secretary, and each medicare contractor insofar as it provides services (including claims processing) for providers of services, physicians, practitioners, facilities, or suppliers, shall maintain an Internet site which—

(1) provides answers in an easily accessible format to frequently asked questions, and

(2) includes all materials published by the Secretary or the contractor, respectively, relating to such providers of services, physicians, practitioners, facilities, and suppliers under the programs under this title and title XI insofar as it relates to such programs.

(c) TAILORING EDUCATION AND TRAINING ACTIVITIES FOR SMALL PROVIDERS OR SUPPLIERS.—

(1) **IN GENERAL.**—Insofar as a medicare contractor conducts education and training activities, it shall take into consideration the special needs of small providers of services or suppliers (as defined in paragraph (2)). Such education and training activities for small providers or services and suppliers may include the provision of technical assistance (such as review of billing systems and internal controls to determine program compliance and to suggest more efficient and effective means of achieving such compliance).

(2) **SMALL PROVIDER OF SERVICES OR SUPPLIER.**—In this subsection, the term “small provider of services or supplier” means—

(A) an institutional provider of services with fewer than 25 full-time-equivalent employees; or

(B) a physician, practitioner, facility, or supplier with fewer than 10 full-time-equivalent employees.

(d) ENCOURAGEMENT OF PARTICIPATION IN EDUCATION PROGRAM ACTIVITIES.—A medicare contractor may not use a record of attendance at (or failure to attend) educational activities or other information gathered during an educational program conducted under this section or otherwise by the Secretary to select or track providers of services, physicians, practitioners, facilities, or suppliers for the purpose of conducting any type of audit or prepayment review.

(e) CONSTRUCTION.—Nothing in this section or section 1893(g) shall be construed as providing for disclosure by a medicare contractor of information that would compromise pending law enforcement activities or reveal findings of law enforcement-related audits.

(f) DEFINITIONS.—For purposes of this section and section 1817(k)(4)(C), the term “medicare contractor” includes the following:

(1) A medicare administrative contractor with a contract under section 1874A, a fiscal intermediary with a contract under section 1816, and a carrier with a contract under section 1842.

(2) An eligible entity with a contract under section 1893.

Such term does not include, with respect to activities of a specific provider of services, physician, practitioner, facility, or supplier an entity that has no authority under this title or title XI with respect to such activities and such provider of services, physician, practitioner, facility, or supplier.

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**MEDICARE, MEDICAID, AND SCHIP BENEFITS
IMPROVEMENT AND PROTECTION ACT OF 2000**

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**TITLE V—PROVISIONS RELATING TO
PARTS A AND B**

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**Subtitle C—Changes in Medicare Coverage
and Appeals Process**

SEC. 521. REVISIONS TO MEDICARE APPEALS PROCESS.

(a) * * *

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[(c) CONFORMING AMENDMENT.—Section 1154(e) (42 U.S.C. 1320c-3(e)) is amended by striking paragraphs (2), (3), and (4).]

(d) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to initial determinations made on or after October 1, [2002] 2003.

SEC. 522. REVISIONS TO MEDICARE COVERAGE PROCESS.

(a) * * *

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(d) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to—

(1) * * *

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on or after October 1, [2001] 2002.

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