

MEDICARE REGULATORY AND CONTRACTING REFORM ACT
OF 2001

NOVEMBER 13, 2001.—Ordered to be printed

Mr. THOMAS, from the Committee on Ways and Means,
submitted the following

R E P O R T

[To accompany H.R. 2768]

[Including cost estimate of the Congressional Budget Office]

The Committee on Ways and Means, to whom was referred the bill (H.R. 2768) to amend title XVIII of the Social Security Act to provide regulatory relief and contracting flexibility under the Medicare Program, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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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 and Contracting 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) 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. Issuance of regulations.
- Sec. 3. Compliance with changes in regulations and policies.
- Sec. 4. Increased flexibility in medicare administration.
- Sec. 5. Provider education and technical assistance.
- Sec. 6. Small provider technical assistance demonstration program.
- Sec. 7. Medicare Provider Ombudsman; Medicare Beneficiary Ombudsman.
- Sec. 8. Provider appeals.
- Sec. 9. Recovery of overpayments and prepayment review; enrollment of providers.
- Sec. 10. Beneficiary outreach demonstration program.
- Sec. 11. Policy development regarding evaluation and management (E & M) documentation guidelines.
- Sec. 12. Improvement in oversight of technology and coverage.
- Sec. 13. Miscellaneous provisions.

(d) CONSTRUCTION.—Nothing in this Act shall be construed—

(1) 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); or

(2) 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.

Furthermore, the consolidation of medicare administrative contracting set forth in this Act does not constitute consolidation of the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund or reflect any position on that issue.

(e) USE OF TERM SUPPLIER IN MEDICARE.—Section 1861 (42 U.S.C. 1395x) is amended by inserting after subsection (c) the following new subsection:

“Supplier

“(d) The term ‘supplier’ means, unless the context otherwise requires, a physician or other practitioner, a facility, or other entity (other than a provider of services) that furnishes items or services under this title.”.

SEC. 2. 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) The Secretary shall issue proposed or final (including interim final) regulations to carry out this title only on one business day of every month unless publication on another date is necessary to comply with requirements under law.

“(2) The Secretary shall coordinate issuance of new regulations relating to a category of provider of services or suppliers based on an analysis of the collective impact of regulatory changes on that category of providers or suppliers.”.

(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 Secretary of Health and Human Services shall submit to Congress a report on the feasibility of requiring that regulations described in section 1871(d) of the Social Security Act only be promulgated on a single day every calendar quarter.

(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 RULES.—

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

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

“(B) 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. If the Secretary intends to vary such timeline with respect to the publication of a final regulation, the Secretary shall cause to have published in the Federal Register notice of the different timeline by not later than the end of the comment period respecting such regulation. Such notice shall include a brief explanation of the justification for such variation.

“(C) In the case of interim final regulations, upon the expiration of the regular timeline established under this paragraph for the publication of a final regulation after opportunity for public comment, the interim final regulation shall not continue in effect unless the Secretary publishes a notice of continuation of the regulation that includes an explanation of why the regular timeline was not complied with. If such a notice is published, the regular timeline for publication of the final regulation shall be treated as having begun again as of the date of publication of the notice.

“(D) The Secretary shall annually submit to Congress a report that describes the instances in which the Secretary failed to publish a final regulation within the applicable timeline under this paragraph and that provides an explanation for such failures.”.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on the date of the enactment of this Act. The Secretary of Health and Human Services 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) If the Secretary publishes notice of proposed rulemaking relating to a regulation (including an interim final regulation), insofar as such final regulation includes a provision that is not a logical outgrowth of such notice of proposed rulemaking, 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. 3. COMPLIANCE WITH CHANGES IN REGULATIONS AND POLICIES.

(a) NO RETROACTIVE APPLICATION OF SUBSTANTIVE CHANGES; TIMELINE FOR COMPLIANCE WITH SUBSTANTIVE CHANGES AFTER NOTICE.—Section 1871 (42 U.S.C. 1395hh), as amended by section 2(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 date the change was issued, unless the Secretary determines that such retroactive application would have a positive impact on beneficiaries or providers of services and suppliers or would be necessary to comply with statutory requirements.

“(B) A substantive change in regulations, manual instructions, interpretative rules, statements of policy, or guidelines of general applicability under this title shall not become effective until at least 30 days after the Secretary issues the substantive change.

“(C) No action shall be taken against a provider of services or supplier with respect to noncompliance with such a substantive change for items and services furnished before the effective date of such a change.”.

(b) RELIANCE ON GUIDANCE.—Section 1871(e), as added by subsection (a), is further amended by adding at the end the following new paragraph:

“(2)(A) If—

“(i) a provider of services or supplier follows the written guidance (which may be transmitted electronically) provided by the Secretary or by a medicare contractor (as defined in section 1889(g)) acting within the scope of the contractor’s contract authority, with respect to the furnishing of items or services and submission of a claim for benefits for such items or services with respect to such provider or supplier;

“(ii) the Secretary determines that the provider of services or supplier has accurately presented the circumstances relating to such items, services, and claim to the contractor in writing; and

“(iii) the guidance was in error;

the provider of services or supplier shall not be subject to any sanction (including any penalty or requirement for repayment of any amount) if the provider of services or supplier reasonably relied on such guidance.

“(B) Subparagraph (A) shall not be construed as preventing the recoupment or repayment (without any additional penalty) relating to an overpayment insofar as the overpayment was solely the result of a clerical or technical operational error.”.

(c) GAO STUDY ON ADVISORY OPINION AUTHORITY.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study to determine the feasibility and appropriateness of establishing in the

Secretary of Health and Human Services and the Secretary's contractors authority to provide legally binding advisory opinions on appropriate interpretation and application of regulations to carry out the medicare program under title XVIII of the Social Security Act. Such study shall examine the appropriate timeframe for issuing such advisory opinions, as well as the need for additional staff and funding to provide such opinions.

(2) REPORT.—The Comptroller General shall submit to Congress a report on the study conducted under paragraph (1) by not later than January 1, 2003.

SEC. 4. 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 entity to serve as a medicare administrative contractor with respect to the performance of any or all of the functions described in paragraph (3) or parts of those functions (or, to the extent provided in a contract, to secure performance thereof by other entities).

“(2) 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 or supplier (or class of such providers of services 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 or supplier or class of provider of services or supplier.

“(3) FUNCTIONS DESCRIBED.—The functions referred to in paragraph (1) 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, 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.—Providing education and outreach to individuals entitled to benefits under part A or enrolled under part B, or both, and providing assistance to those individuals with specific issues, concerns or problems.

“(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 or suppliers.

“(E) COMMUNICATION WITH PROVIDERS.—Communicating to providers of services and suppliers any information or instructions furnished to the medicare administrative contractor by the Secretary and serving as a channel of communication from providers of services and suppliers to the Secretary.

“(F) PROVIDER EDUCATION AND TECHNICAL ASSISTANCE.—Performing the functions relating to provider education, training, and technical assistance.

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

“(4) 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 activities 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.

“(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, taking into account performance quality as well as price and other factors.

“(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.—Functions may be transferred among medicare administrative contractors consistent with the provisions of this paragraph. The Secretary shall ensure that performance quality is considered in such transfers.

“(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, quality of services provided, and other matters as the Secretary finds pertinent.

“(3) DEVELOPMENT OF SPECIFIC PERFORMANCE REQUIREMENTS.—In developing contract performance requirements, the Secretary shall develop performance requirements to carry out the specific requirements applicable under this title to a function described in subsection (a)(3). In developing such requirements, the Secretary may consult with providers of services and suppliers and organizations and agencies performing functions necessary to carry out the purposes of this section with respect to such performance requirements.

“(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)(3)(B).

“(2) PROHIBITION ON MANDATES FOR CERTAIN DATA COLLECTION.—The Secretary may not require, as a condition of entering into 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.—A medicare administrative contractor shall be liable to the United States for a payment referred to in paragraph (1) or (2) if, in connection with such payment, an individual referred to in either such paragraph acted with gross negligence or intent to defraud the United States.

“(4) INDEMNIFICATION BY SECRETARY.—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, if due care was exercised by the contractor or person 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 of Health and Human Services 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”;
 - (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.—Except as otherwise provided in this subsection, the amendments made by this section shall take effect on October 1, 2003, and the Secretary of Health and Human Services is authorized to take such steps before such date as may be necessary to implement such amendments on a timely basis.

(2) GENERAL TRANSITION RULES.—The Secretary shall take such steps 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), consistent with the requirements under such section to competitively bid all contracts within 5 years after the effective date in paragraph (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), 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).

SEC. 5. 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 (i), including under section 1893) in order to maximize the effectiveness of Federal education efforts for providers of services 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 of Health and Human Services 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 4(a)(1), is amended by adding at the end the following new subsection:

“(e) INCENTIVES TO IMPROVE CONTRACTOR PERFORMANCE IN PROVIDER EDUCATION AND OUTREACH.—

“(1) METHODOLOGY TO MEASURE CONTRACTOR ERROR RATES.—In order to give medicare administrative contractors an incentive to implement effective education and outreach programs for providers of services and suppliers, the Secretary shall, in consultation with representatives of providers and suppliers, develop and implement by October 1, 2003, a methodology to measure the specific claims payment error rates of such contractors in the processing or reviewing of medicare claims.

“(2) IDENTIFICATION OF BEST PRACTICES.—The Secretary shall identify the best practices developed by individual medicare administrative contractors for edu-

cating providers of services and suppliers and how to encourage the use of such best practices nationwide.”.

(2) REPORT.—Not later than October 1, 2003, the Secretary of Health and Human Services shall submit to Congress a report that describes how the Secretary intends to use the methodology developed under section 1874A(e)(1) of the Social Security Act, as added by paragraph (1), in assessing medicare contractor performance in implementing effective education and outreach programs, including whether to use such methodology as the basis for performance bonuses. The report shall include an analysis of the sources of identified errors and potential changes in systems of contractors and rules of the Secretary that could reduce claims error rates.

(c) PROVISION OF ACCESS TO AND PROMPT RESPONSES FROM MEDICARE ADMINISTRATIVE CONTRACTORS.—

(1) IN GENERAL.—Section 1874A, as added by section 4(a)(1) and as amended by subsection (b), is further amended by adding at the end the following new subsection:

“(f) RESPONSE TO INQUIRIES; TOLL-FREE LINES.—

“(1) CONTRACTOR RESPONSIBILITY.—Each medicare administrative contractor shall, for those providers of services and suppliers which submit claims to the contractor for claims processing—

“(A) respond in a clear, concise, and accurate manner to specific billing and cost reporting questions of providers of services and suppliers;

“(B) maintain a toll-free telephone number at which providers of services and suppliers may obtain information regarding billing, coding, and other appropriate information under this title;

“(C) maintain a system for identifying (and disclosing, upon request) who provides the information referred to in subparagraphs (A) and (B); and

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

“(2) EVALUATION.—In conducting evaluations of individual medicare administrative contractors, the Secretary shall take into account the results of the monitoring conducted under paragraph (1)(D). The Secretary shall, in consultation with organizations representing providers of services and suppliers, establish standards relating to the accuracy, consistency, and timeliness of the information so provided.”.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect October 1, 2003.

(d) IMPROVED PROVIDER EDUCATION AND TRAINING.—

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

“(b) ENHANCED EDUCATION AND TRAINING.—

“(1) ADDITIONAL RESOURCES.—For each of fiscal years 2003 and 2004, there are authorized to be appropriated to the Secretary (in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) \$10,000,000 .

“(2) USE.—The funds made available under paragraph (1) shall be used to increase the conduct by medicare contractors of education and training of providers of services and suppliers regarding billing, coding, and other appropriate items.

“(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 tailor such activities to meet the special needs of small providers of services or suppliers (as defined in paragraph (2)).

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

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

“(B) a supplier with fewer than 10 full-time-equivalent employees.”.

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

(e) REQUIREMENT TO MAINTAIN INTERNET SITES.—

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

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

“(1) provides answers in an easily accessible format to frequently asked questions, and
 “(2) includes other published materials of the contractor,
 that relate to providers of services 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.

(f) ADDITIONAL PROVIDER EDUCATION PROVISIONS.—

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

“(e) 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 or suppliers for the purpose of conducting any type of audit or prepayment review.

“(f) CONSTRUCTION.—Nothing in this section or section 1893(g) shall be construed as providing for disclosure by a medicare contractor—

“(1) of the screens used for identifying claims that will be subject to medical review; or

“(2) of information that would compromise pending law enforcement activities or reveal findings of law enforcement-related audits.

“(g) DEFINITIONS.—For purposes of this section, the term ‘medicare contractor’ includes the following:

“(1) A medicare administrative contractor with a contract under section 1874A, including 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 or supplier an entity that has no authority under this title or title IX with respect to such activities and such provider of services or supplier.”.

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

SEC. 6. SMALL PROVIDER TECHNICAL ASSISTANCE DEMONSTRATION PROGRAM.

(a) ESTABLISHMENT.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall establish a demonstration program (in this section referred to as the “demonstration program”) under which technical assistance described in paragraph (2) is made available, upon request and on a voluntary basis, to small providers of services or suppliers in order to improve compliance with the applicable requirements of the programs under medicare program under title XVIII of the Social Security Act (including provisions of title XI of such Act insofar as they relate to such title and are not administered by the Office of the Inspector General of the Department of Health and Human Services).

(2) FORMS OF TECHNICAL ASSISTANCE.—The technical assistance described in this paragraph is—

(A) evaluation and recommendations regarding billing and related systems; and

(B) information and assistance regarding policies and procedures under the medicare program, including coding and reimbursement.

(3) SMALL PROVIDERS OF SERVICES OR SUPPLIERS.—In this section, the term “small providers of services or suppliers” means—

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

(B) a supplier with fewer than 10 full-time-equivalent employees.

(b) QUALIFICATION OF CONTRACTORS.—In conducting the demonstration program, the Secretary of Health and Human Services shall enter into contracts with qualified organizations (such as peer review organizations or entities described in section 1889(g)(2) of the Social Security Act, as inserted by section 5(f)(1) with appropriate expertise with billing systems of the full range of providers of services and suppliers to provide the technical assistance. In awarding such contracts, the Secretary shall consider any prior investigations of the entity’s work by the Inspector General of Department of Health and Human Services or the Comptroller General of the United States.

(c) DESCRIPTION OF TECHNICAL ASSISTANCE.—The technical assistance provided under the demonstration program shall include a direct and in-person examination of billing systems and internal controls of small providers of services or suppliers

to determine program compliance and to suggest more efficient or effective means of achieving such compliance.

(d) AVOIDANCE OF RECOVERY ACTIONS FOR PROBLEMS IDENTIFIED AS CORRECTED.—The Secretary of Health and Human Services shall provide that, absent evidence of fraud and notwithstanding any other provision of law, any errors found in a compliance review for a small provider of services or supplier that participates in the demonstration program shall not be subject to recovery action if the technical assistance personnel under the program determine that—

(1) the problem that is the subject of the compliance review has been corrected to their satisfaction within 30 days of the date of the visit by such personnel to the small provider of services or supplier; and

(2) such problem remains corrected for such period as is appropriate.

(e) GAO EVALUATION.—Not later than 2 years after the date of the date the demonstration program is first implemented, the Comptroller General, in consultation with the Inspector General of the Department of Health and Human Services, shall conduct an evaluation of the demonstration program. The evaluation shall include a determination of whether claims error rates are reduced for small providers of services or suppliers who participated in the program and the extent of improper payments made as a result of the demonstration program. The Comptroller General shall submit a report to the Secretary and the Congress on such evaluation and shall include in such report recommendations regarding the continuation or extension of the demonstration program.

(f) FINANCIAL PARTICIPATION BY PROVIDERS.—The provision of technical assistance to a small provider of services or supplier under the demonstration program is conditioned upon the small provider of services or supplier paying an amount estimated (and disclosed in advance of a provider's or supplier's participation in the program) to be equal to 25 percent of the cost of the technical assistance.

(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Secretary of Health and Human Services (in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) to carry out the demonstration program—

(1) for fiscal year 2003, \$1,000,000, and

(2) for fiscal year 2004, \$6,000,000.

SEC. 7. MEDICARE PROVIDER OMBUDSMAN; MEDICARE BENEFICIARY OMBUDSMAN.

(a) MEDICARE PROVIDER OMBUDSMAN.—Section 1868 (42 U.S.C. 1395ee) is amended—

(1) by adding at the end of the heading the following: “; MEDICARE PROVIDER OMBUDSMAN”;

(2) by inserting “PRACTICING PHYSICIANS ADVISORY COUNCIL.—(1)” after “(a)”;

(3) in paragraph (1), as so redesignated under paragraph (2), by striking “in this section” and inserting “in this subsection”;

(4) by redesignating subsections (b) and (c) as paragraphs (2) and (3), respectively; and

(5) by adding at the end the following new subsection:

“(b) MEDICARE PROVIDER OMBUDSMAN.—The Secretary shall appoint a Medicare Provider Ombudsman. The Ombudsman shall—

“(1) provide assistance, on a confidential basis, to providers of services and suppliers with respect to complaints, grievances, and requests for information concerning the programs under this title (including provisions of title XI insofar as they relate to this title and are not administered by the Office of the Inspector General of the Department of Health and Human Services) and in the resolution of unclear or conflicting guidance given by the Secretary and medicare contractors to such providers of services and suppliers regarding such programs and provisions and requirements under this title and such provisions; and

“(2) submit recommendations to the Secretary for improvement in the administration of this title and such provisions, including—

“(A) recommendations to respond to recurring patterns of confusion in this title and such provisions (including recommendations regarding suspending imposition of sanctions where there is widespread confusion in program administration), and

“(B) recommendations to provide for an appropriate and consistent response (including not providing for audits) in cases of self-identified overpayments by providers of services and suppliers.”.

(b) MEDICARE BENEFICIARY OMBUDSMAN.—Title XVIII is amended by inserting after section 1806 the following new section:

“MEDICARE BENEFICIARY OMBUDSMAN

“SEC. 1807. (a) IN GENERAL.—The Secretary shall appoint within the Department of Health and Human Services a Medicare Beneficiary Ombudsman who shall have expertise and experience in the fields of health care and advocacy.

“(b) DUTIES.—The Medicare Beneficiary Ombudsman shall—

“(1) receive complaints, grievances, and requests for information submitted by a medicare beneficiary, with respect to any aspect of the medicare program;

“(2) provide assistance with respect to complaints, grievances, and requests referred to in paragraph (1), including—

“(A) assistance in collecting relevant information for such beneficiaries, to seek an appeal of a decision or determination made by a fiscal intermediary, carrier, Medicare+Choice organization, or the Secretary; and

“(B) assistance to such beneficiaries with any problems arising from disenrollment from a Medicare+Choice plan under part C; and

“(3) submit annual reports to Congress and the Secretary that describe the activities of the Office and that include such recommendations for improvement in the administration of this title as the Ombudsman determines appropriate.”.

(c) FUNDING.—There are authorized to be appropriated to the Secretary of Health and Human Services (in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) to carry out the provisions of subsection (b) of section 1868 of the Social Security Act (relating to the Medicare Provider Ombudsman), as added by subsection (a)(5) and section 1807 of such Act (relating to the Medicare Beneficiary Ombudsman), as added by subsection (b), such sums as are necessary for fiscal year 2002 and each succeeding fiscal year.

(d) USE OF CENTRAL, TOLL-FREE NUMBER (1-800-MEDICARE).—Section 1804(b) (42 U.S.C. 1395b–2(b)) is amended by adding at the end the following: “The Secretary shall provide, through the toll-free number 1-800-MEDICARE, for a means by which individuals seeking information about, or assistance with, such programs who phone such toll-free number are transferred (without charge) to appropriate entities for the provision of such information or assistance. Such toll-free number shall be the toll-free number listed for general information and assistance in the annual notice under subsection (a) instead of the listing of numbers of individual contractors.”.

SEC. 8. PROVIDER APPEALS.

(a) MEDICARE ADMINISTRATIVE LAW JUDGES.—Section 1869 (42 U.S.C. 1395ff), as amended by section 521(a) of Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (114 Stat. 2763A–534), as enacted into law by section 1(a)(6) of Public Law 106–554, is amended by adding at the end the following new subsection:

“(g) MEDICARE ADMINISTRATIVE LAW JUDGES.—

“(1) TRANSITION PLAN.—Not later than October 1, 2003, the Commissioner of Social Security and the Secretary shall develop and implement a plan under which the functions of administrative law judges responsible for hearing cases under this title (and related provisions in title XI) shall be transferred from the responsibility of the Commissioner and the Social Security Administration to the Secretary and the Department of Health and Human Services. The plan shall include recommendations with respect to—

“(A) the number of administrative law judges and support staff required to hear and decide such cases in a timely manner; and

“(B) funding levels required for fiscal year 2004 and subsequent fiscal years under this subsection to hear such cases in a timely manner.

Nothing in this subsection shall be construed as affecting the independence of administrative law judges from the Department of Health and Human Services and from medicare contractors in carrying out their responsibilities for hearing and deciding cases.

“(2) INCREASED FINANCIAL SUPPORT.—In addition to any amounts otherwise appropriated, 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 to increase the number of administrative law judges described in paragraph (1) and to improve education and training for such judges and their staffs in carrying out functions under this title, \$5,000,000 for fiscal year 2003 and such sums as are necessary for fiscal year 2004 and each subsequent fiscal year.

“(3) SUBMITTAL OF PLAN TO CONGRESS AND GAO; REPORT OF GAO.—Not later than July 1, 2003, the Secretary shall submit to the Committee on Ways and Means of the House of Representatives, the Committee on Finance of the Senate, and the Comptroller General of the United States the terms of the plan de-

veloped under paragraph (1). No later than September 1, 2003, the Comptroller General shall submit to such Committees a report containing an evaluation of the terms of such plan.”

(b) PROCESS FOR EXPEDITED ACCESS TO JUDICIAL REVIEW.—

(1) IN GENERAL.—Section 1869(b) (42 U.S.C. 1395ff(b)) as amended by Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (114 Stat. 2763A–534), as enacted into law by section 1(a)(6) of Public Law 106–554, is amended—

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

(B) 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) (other than an appeal filed under paragraph (1)(F)) 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 it 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 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 no review panel has 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 no review panel has the 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 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 AMOUNTS IN CONTROVERSY.—Where a provider of services or supplier seeks judicial review pursuant to this paragraph, the amount in controversy 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 Hospital 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 or suppliers under this Act.

“(D) REVIEW PANELS.—For purposes of this subsection, a ‘review panel’ is an administrative law judge, the Departmental Appeals Board, a qualified independent contractor (as defined in subsection (c)(2)), or an entity des-

ignated by the Secretary for purposes of making determinations under this paragraph.”

(2) APPLICATION TO TERMINATION PROCEEDINGS.—Section 1866(h) (42 U.S.C. 1395cc(h)) is amended by adding at the end the following new paragraph:

“(3) The provisions of section 1869(b)(2) shall apply with respect to determinations described in paragraph (1) in the same manner as they apply to a provider of services that has filed an appeal under section 1869(b)(1).”

(3) EFFECTIVE DATE.—The amendments made by this subsection shall apply to appeals filed on or after October 1, 2002.

(c) REQUIRING FULL AND EARLY PRESENTATION OF EVIDENCE.—

(1) IN GENERAL.—Section 1869(b) (42 U.S.C. 1395ff(b)), as amended by Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (114 Stat. 2763A–534), as enacted into law by section 1(a)(6) of Public Law 106–554, and as amended by subsection (b), is further amended by adding at the end the following new paragraph:

“(3) REQUIRING FULL AND EARLY PRESENTATION OF EVIDENCE BY PROVIDERS.—A provider of services or supplier may not introduce evidence in any appeal under this section that was not presented at the reconsideration conducted by the qualified independent contractor under subsection (c), unless there is good cause which precluded the introduction of such evidence at or before that reconsideration.”

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

SEC. 9. RECOVERY OF OVERPAYMENTS AND PREPAYMENT REVIEW; ENROLLMENT OF PROVIDERS.

(a) RECOVERY OF OVERPAYMENTS AND PREPAYMENT REVIEW.—Section 1893 (42 U.S.C. 1395ddd) is amended by adding at the end the following new subsections:

“(f) RECOVERY OF OVERPAYMENTS AND PREPAYMENT REVIEW.—

“(1) USE OF REPAYMENT PLANS.—

“(A) IN GENERAL.—If the repayment, within 30 days by a provider of services or supplier, of an overpayment under this title would constitute a hardship (as defined in subparagraph (B)), subject to subparagraph (C), the Secretary shall enter into a plan (which meets terms and conditions determined to be appropriate by the Secretary) with the provider of services or supplier for the offset or repayment of such overpayment over a period of not longer than 3 years, or in the case of extreme hardship (as determined by the Secretary) over a period of not longer than 5 years. Interest shall accrue on the balance through the period of repayment.

“(B) HARDSHIP.—

“(i) IN GENERAL.—For purposes of subparagraph (A), the repayment of an overpayment (or overpayments) within 30 days is deemed to constitute a hardship if—

“(I) in the case of a provider of services that files cost reports, the aggregate amount of the overpayments exceeds 10 percent of the amount paid under this title to the provider of services for the cost reporting period covered by the most recently submitted cost report; or

“(II) in the case of another provider of services or supplier, the aggregate amount of the overpayments exceeds 10 percent of the amount paid under this title to the provider of services or supplier for the previous calendar year.

“(ii) RULE OF APPLICATION.—The Secretary shall establish rules for the application of this subparagraph in the case of a provider of services or supplier that was not paid under this title during the previous year or was paid under this title only during a portion of that year.

“(iii) TREATMENT OF PREVIOUS OVERPAYMENTS.—If a provider of services or supplier has entered into a repayment plan under subparagraph (A) with respect to a specific overpayment amount, such payment amount under the repayment plan shall not be taken into account under clause (i) with respect to subsequent overpayment amounts.

“(C) EXCEPTIONS.—Subparagraph (A) shall not apply if the Secretary has reason to suspect that the provider of services or supplier may file for bankruptcy or otherwise cease to do business or if 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 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.

“(2) LIMITATION ON RECOUPMENT UNTIL DETERMINATION BY QUALIFIED INDEPENDENT CONTRACTOR.—

“(A) IN GENERAL.—In the case of a provider of services 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 paragraph (9)) to recoup the overpayment until the date the decision on the reconsideration has been rendered.

“(B) COLLECTION WITH INTEREST.—Insofar as the determination on such appeal is against the provider of services or supplier, interest on the overpayment shall accrue on and after the date of the original notice of overpayment. Insofar as such determination against the provider of services or supplier is later reversed, the Secretary shall provide for repayment of the amount recouped plus interest at the same rate as would apply under the previous sentence for the period in which the amount was recouped.

“(3) STANDARDIZATION OF RANDOM PREPAYMENT REVIEW.—

“(A) IN GENERAL.—A medicare contractor may conduct random prepayment review only to develop a contractor-wide or program-wide claims payment error rates or under such additional circumstances as may be provided under regulations, developed in consultation with providers of services and suppliers.

“(B) CONSTRUCTION.—Nothing in subparagraph (A) shall be construed as preventing the denial of payments for claims actually reviewed under a random prepayment review.

“(4) 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).

“(5) PROVISION OF SUPPORTING DOCUMENTATION.—In the case of a provider of services or supplier with respect to which amounts were previously overpaid, a medicare contractor may 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.

“(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 or supplier a consent settlement, the Secretary shall—

“(i) communicate to the provider of services or supplier in a non-threatening manner that, based on a review of the medical records requested by the Secretary, a preliminary analysis indicates that there would be an overpayment; and

“(ii) provide for a 45-day period during which the provider of services 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 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 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 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 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 or supplier agrees not to appeal the claims involved.

“(7) LIMITATIONS ON NON-RANDOM PREPAYMENT REVIEW.—

“(A) LIMITATION ON INITIATION OF NON-RANDOM PREPAYMENT REVIEW.—A medicare contractor may not initiate non-random prepayment review of a provider of services or supplier based on the initial identification by that provider of services or supplier of an improper billing practice unless there is a sustained or high level of payment error (as defined in paragraph (4)(A)).

“(B) 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.

“(8) 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 or supplier under this title, the contractor shall provide the provider of services or supplier with written notice 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 or supplier under this title, the contractor shall provide for an exit conference with the provider or supplier during which the contractor shall—

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

“(ii) inform the provider of services or supplier of the appeal rights under this title;

“(iii) give the provider of services 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 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 or reveal findings of law enforcement-related audits.

“(9) DEFINITIONS.—For purposes of this subsection:

“(A) MEDICARE CONTRACTOR.—The term ‘medicare contractor’ has the meaning given such term in section 1889(g).

“(B) RANDOM PREPAYMENT REVIEW.—The term ‘random prepayment review’ means a demand for the production of records or documentation absent cause with respect to a claim.

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

(b) PROVIDER ENROLLMENT PROCESS; RIGHT OF APPEAL.—

(1) IN GENERAL.—Section 1866 (42 U.S.C. 1395cc) is amended—

(A) by adding at the end of the heading the following: “; ENROLLMENT PROCESSES”; and

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

“(j) ENROLLMENT PROCESS FOR PROVIDERS OF SERVICES AND SUPPLIERS.—

“(1) IN GENERAL.—The Secretary shall establish by regulation a process for the enrollment of providers of services and suppliers under this title.

“(2) APPEAL PROCESS.—Such process shall provide—

“(A) a method by which providers of services and suppliers whose application to enroll (or, if applicable, to renew enrollment) are denied are provided a mechanism to appeal such denial; and

“(B) prompt deadlines for actions on applications for enrollment (and, if applicable, renewal of enrollment) and for consideration of appeals.”

(2) EFFECTIVE DATE.—The Secretary of Health and Human Services shall provide for the establishment of the enrollment and appeal process under the amendment made by paragraph (1) within 6 months after the date of the enactment of this Act.

(c) PROCESS FOR CORRECTION OF MINOR ERRORS AND OMISSIONS ON CLAIMS WITHOUT PURSUING APPEALS PROCESS.—The Secretary of Health and Human Services

shall develop, in consultation with appropriate medicare contractors (as defined in section 1889(g) of the Social Security Act, as inserted by section 5(f)(1) and representatives of providers of services and suppliers, a process whereby, in the case of minor errors or omissions that are detected in the submission of claims under the programs under title XVIII of such Act, a provider of services 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.

SEC. 10. BENEFICIARY OUTREACH DEMONSTRATION PROGRAM.

(a) **IN GENERAL.**—The Secretary of Health and Human Services shall establish a demonstration program (in this section 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 regarding the medicare program at the location of existing local offices of the Social Security Administration.

(b) **LOCATIONS.**—

(1) **IN GENERAL.**—The demonstration program shall be conducted in at least 6 offices or areas. Subject to paragraph (2), in selecting such offices and areas, the Secretary shall provide preference for offices with a high volume of visits by medicare beneficiaries.

(2) **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.

(c) **DURATION.**—The demonstration program shall be conducted over a 3-year period.

(d) **EVALUATION AND REPORT.**—

(1) **EVALUATION.**—The Secretary shall provide for an evaluation of the demonstration program. Such evaluation shall include an analysis of—

(A) utilization of, and beneficiary satisfaction with, the assistance provided under the program; and

(B) the cost-effectiveness of providing beneficiary assistance through out-stationing medicare specialists at local social security offices.

(2) **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.

SEC. 11. POLICY DEVELOPMENT REGARDING EVALUATION AND MANAGEMENT (E & M) DOCUMENTATION GUIDELINES.

(a) **IN GENERAL.**—The Secretary of Health and Human Services 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 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 modifications to 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 conducted appropriate outreach to physicians for education and training with respect to the guidelines.

The Secretary shall 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) **LENGTH AND CONSULTATION.**—Each pilot project under this subsection shall—

(A) be of sufficient length to allow for preparatory physician and medicare contractor education, analysis, and use and assessment of potential evaluation and management guidelines; and

(B) be conducted, in development and throughout the planning and operational stages of the project, in consultation with practicing physicians.

(2) 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) 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 one shall be conducted in a setting other than a teaching setting.

(3) 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.

(4) STUDY OF IMPACT.—Each pilot project shall examine the effect of the modified 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.

(c) OBJECTIVES FOR EVALUATION AND MANAGEMENT GUIDELINES.—The objectives for modified evaluation and management documentation guidelines developed by the Secretary shall be to—

(1) enhance 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) STUDY OF SIMPLER, ALTERNATIVE SYSTEMS OF DOCUMENTATION FOR PHYSICIAN CLAIMS.—

(1) STUDY.—The Secretary of Health and Human Services shall carry out a study of the matters described in paragraph (2).

(2) MATTERS DESCRIBED.—The matters referred to in paragraph (1) are—

(A) the development of a simpler, alternative system of requirements for documentation accompanying claims for evaluation and management physician services for which payment is made under title XVIII of the Social Security Act; and

(B) consideration of systems other than current coding and documentation requirements for payment for such physician services.

(3) CONSULTATION WITH PRACTICING PHYSICIANS.—In designing and carrying out the study under paragraph (1), the Secretary shall consult with practicing physicians, including physicians who are part of group practices.

(4) APPLICATION OF HIPAA UNIFORM CODING REQUIREMENTS.—In developing an alternative system under paragraph (2), the Secretary shall consider requirements of administrative simplification under part C of title XI of the Social Security Act.

(5) REPORT TO CONGRESS.—(A) The Secretary shall submit to Congress a report on the results of the study conducted under paragraph (1).

(B) The Medicare Payment Advisory Commission shall conduct an analysis of the results of the study included in the report under subparagraph (A) and shall submit a report on such analysis to Congress.

(e) STUDY ON APPROPRIATE CODING OF CERTAIN EXTENDED OFFICE VISITS.—The Secretary shall conduct a study of the appropriateness of coding in cases of extended office visits in which there is no diagnosis made. The Secretary shall submit a report to Congress on such study and shall include recommendations on how to code appropriately for such visits in a manner that takes into account the amount of time the physician spent with the patient.

(f) 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. 12. IMPROVEMENT IN OVERSIGHT OF TECHNOLOGY AND COVERAGE.**(a) IMPROVED COORDINATION BETWEEN FDA AND CMS ON COVERAGE OF BREAK-THROUGH MEDICAL DEVICES.—**

(1) **IN GENERAL.**—Upon request by an applicant and to the extent feasible (as determined by the Secretary of Health and Human Services), the Secretary shall, in the case of a class III medical device that is subject to premarket approval under section 515 of the Federal Food, Drug, and Cosmetic Act, coordinate reviews of coverage decisions under title XVIII of the Social Security Act with the review for application for premarket approval conducted by the Food and Drug Administration under such section. Such coordination shall include the sharing of appropriate information.

(2) **PUBLICATION OF PLAN.**—Not later than 6 months after the date of the enactment of this Act, the Secretary shall submit to appropriate Committees of Congress a report that contains the plan for improving such coordination and for shortening the time lag between the premarket approval by the Food and Drug Administration and coding and coverage decisions by the Centers for Medicare & Medicaid Services.

(3) **CONSTRUCTION.**—Nothing in this subsection shall be construed as changing the criteria for coverage of a medical device under title XVIII of the Social Security Act nor premarket approval by the Food and Drug Administration.

(b) COUNCIL FOR TECHNOLOGY AND INNOVATION.—

(1) **ESTABLISHMENT.**—The Secretary of Health and Human Services shall establish a Council for Technology and Innovation within the Centers for Medicare & Medicaid Services (in this section referred to as “CMS”).

(2) **COMPOSITION.**—The Council shall be composed of senior CMS staff and clinicians and shall be chaired by the Executive Coordinator for Technology and Innovation (appointed or designated under paragraph (4)).

(3) **DUTIES.**—The Council shall coordinate the activities of coverage, coding, and payment processes under title XVIII of the Social Security Act with respect to new technologies and procedures, including new drug therapies, and shall coordinate the exchange of information on new technologies between CMS and other entities that make similar decisions.

(4) **EXECUTIVE COORDINATOR FOR TECHNOLOGY AND INNOVATION.**—The Secretary shall appoint (or designate) a noncareer appointee (as defined in section 3132(a)(7) of title 5, United States Code) who shall serve as the Executive Coordinator for Technology and Innovation. Such executive coordinator shall report to the Administrator of CMS, shall chair the Council, shall oversee the execution of its duties, and shall serve as a single point of contact for outside groups and entities regarding the coverage, coding, and payment processes under title XVIII of the Social Security Act.

(c) GAO STUDY ON IMPROVEMENTS IN EXTERNAL DATA COLLECTION FOR USE IN THE MEDICARE INPATIENT PAYMENT SYSTEM.—

(1) **STUDY.**—The Comptroller General of the United States shall conduct a study that analyzes which external data can be collected in a shorter time frame by the Centers For Medicare & Medicaid Services for use in computing payments for inpatient hospital services. The study may include an evaluation of the feasibility and appropriateness of using of quarterly samples or special surveys or any other methods. The study shall include an analysis of whether other executive agencies, such as the Bureau of Labor Statistics in the Department of Commerce, are best suited to collect this information.

(2) **REPORT.**—By not later than October 1, 2002, the Comptroller General shall submit a report to Congress on the study under paragraph (1).

(d) APPLICATION OF OSHA BLOODBORNE PATHOGENS STANDARD TO CERTAIN HOSPITALS.—

(1) **IN GENERAL.**—Section 1866 (42 U.S.C. 1395cc) is amended—

(A) in subsection (a)(1)—

- (i) in subparagraph (R), by striking “and” at the end;
- (ii) in subparagraph (S), by striking the period at the end and insert “, and”; and
- (iii) by inserting after subparagraph (S) the following new subparagraph:

“(T) in the case of hospitals that are not otherwise subject to the Occupational Safety and Health Act of 1970, to comply with the Bloodborne Pathogens standard under section 1910.1030 of title 29 of the Code of Federal Regulations (or as subsequently redesignated).”; and

(B) by adding at the end of subsection (b) the following new paragraph:
“(4)(A) A hospital that fails to comply with the requirement of subsection (a)(1)(T) (relating to the Bloodborne Pathogens standard) is subject to a civil money penalty

in an amount described in subparagraph (B), but is not subject to termination of an agreement under this section.

“(B) The amount referred to in subparagraph (A) is an amount that is similar to the amount of civil penalties that may be imposed under section 17 of the Occupational Safety and Health Act of 1970 for a violation of the Bloodborne Pathogens standard referred to in subsection (a)(1)(T) by a hospital that is subject to the provisions of such Act.

“(C) A civil money penalty under this paragraph shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A are imposed and collected under that section.”.

(2) EFFECTIVE DATE.—The amendments made by this paragraph (1) shall apply to hospitals as of July 1, 2002.

(e) IOM STUDY ON LOCAL COVERAGE DETERMINATIONS.—

(1) STUDY.—The Secretary shall enter into an arrangement with the Institute of Medicine of the National Academy of Sciences under which the Institute shall conduct a study on the capabilities and information available for local coverage determinations (including the application of local medical review policies) under the medicare program under title XVIII of the Social Security Act. Such study shall examine—

(A) the consistency of the definitions used in such determinations;

(B) the extent to which such determinations are based on evidence, including medical and scientific evidence;

(C) the advantages and disadvantages of local coverage decisionmaking, including the flexibility it offers for ensuring timely patient access to new medical technology for which data are still be collected;

(D) whether local coverage determinations are made, in the absence of adequate data, in order to collect such data in a manner that results in coverage of experimental items or services; and

(E) the advantages and disadvantages of maintaining local medicare contractor advisory committees that can advise on local coverage decisions based on an open, collaborative public process.

(2) REPORT.—Such arrangement shall provide that the Institute shall submit to the Secretary a report on such study by not later than 3 years after the date of the enactment of this Act. The Secretary shall promptly transmit a copy of such report to Congress.

(f) 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. 13. MISCELLANEOUS PROVISIONS.

(a) TREATMENT OF HOSPITALS FOR CERTAIN SERVICES UNDER MEDICARE SECONDARY PAYOR (MSP) PROVISIONS.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall not require a hospital (including a critical access hospital) to ask questions (or obtain information) relating to the application of section 1862(b) of the Social Security Act (relating to medicare secondary payor provisions) in the case of reference laboratory services described in paragraph (2), if the Secretary does not impose such requirement in the case of such services furnished by an independent laboratory.

(2) REFERENCE LABORATORY SERVICES DESCRIBED.—Reference laboratory services described in this paragraph are clinical laboratory diagnostic tests (or the interpretation of such tests, or both) furnished without a face-to-face encounter between the beneficiary and the hospital involved and in which the hospital submits a claim only for such test or interpretation.

(b) CLARIFICATION OF PRUDENT LAYPERSON TEST FOR EMERGENCY SERVICES UNDER THE MEDICARE FEE-FOR-SERVICE PROGRAM.—

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

“(d) In the case of hospital services and physicians’ services that—

“(1) are furnished, to an individual who is not enrolled in a Medicare+Choice plan under part C, by a hospital or a critical access hospital; and

“(2) are needed to evaluate or stabilize an emergency medical condition (as defined in section 1852(d)(3)(B), relating to application of a prudent layperson rule) and that are provided to meet the requirements of section 1867, such services shall be deemed to be reasonable and necessary for the diagnosis or treatment of illness or injury for purposes of subsection (a)(1)(A).”.

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

(c) PROMPT SUBMISSION OF OVERDUE REPORTS ON PAYMENT AND UTILIZATION OF OUTPATIENT THERAPY SERVICES.—The Secretary of Health and Human Services shall submit to Congress as expeditiously as practicable the reports required under section 4541(d)(2) of the Balanced Budget Act of 1997 (relating to alternatives to a single annual dollar cap on outpatient therapy) and under section 221(d) of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (relating to utilization patterns for outpatient therapy).

(d) AUTHORIZING USE OF ARRANGEMENTS WITH OTHER HOSPICE PROGRAMS TO PROVIDE CORE HOSPICE SERVICES IN CERTAIN CIRCUMSTANCES.—

(1) IN GENERAL.—Section 1861(dd)(5) (42 U.S.C. 1395x(dd)(5)) is amended by adding at the end the following new subparagraph:

“(D) In extraordinary, exigent, or other non-routine circumstances, such as unanticipated periods of high patient loads, staffing shortages due to illness or other events, or temporary travel of a patient outside a hospice program’s service area, a hospice program may enter into arrangements with another hospice program for the provision by that other program of services described in paragraph (2)(A)(ii)(I). The provisions of paragraph (2)(A)(ii)(II) shall apply with respect to the services provided under such arrangements.”.

(2) CONFORMING PAYMENT PROVISION.—Section 1814(i) (42 U.S.C. 1395f(i)) is amended by adding at the end the following new paragraph:

“(4) In the case of hospice care provided by a hospice program under arrangements under section 1861(dd)(5)(D) made by another hospice program, the hospice program that made the arrangements shall bill and be paid for the hospice care.”.

(3) EFFECTIVE DATE.—The amendments made by this subsection shall apply to hospice care provided on or after the date of the enactment of this Act.

I. INTRODUCTION

A. PURPOSE AND SUMMARY

The primary purpose of H.R. 2768 is to create a more collaborative, less confrontational relationship between providers and the Centers for Medicare and Medicaid Services. H.R. 2768 will diminish the paperwork load required to meet complex and technical regulatory requirements, and allow providers to spend more time with patients. H.R. 2768 streamlines the regulatory process, enhances education and technical assistance for doctors and other health care providers, and protects the rights of providers in the audit and recovery process to ensure that the repayment process is fair and open.

In addition, H.R. 2768 gives the Secretary the tools to manage Medicare program operations efficiently. For the first time, the Centers for Medicare and Medicaid Services will be able to competitively contract with the best entities available to process claims, make payments and answer questions. The Secretary will be free to promote quality by creating incentives for the Medicare Administrative Contractors to provide outstanding service to seniors and health care providers. Contractor reform initiatives will eliminate artificial distinctions between Medicare’s Part A and Part B with regard to contracting practices. But this does not constitute a combination of the Part A and Part B trust funds or any position on that matter.

Finally, HR 2768 includes several provisions to help beneficiaries interact with and better understand the Medicare program, including the establishment of an internal beneficiary ombudsman program, a demonstration program to place Medicare specialist in Social Security offices, and an improved 800-number to facilitate communication between beneficiaries and CMS or its contractors.

B. BACKGROUND AND NEED FOR THE LEGISLATION

H.R. 2768 was developed through months of consultation with health care providers and other experts, including public hearings before the Ways and Means Subcommittee on Health. Working closely with the Bush Administration, the Subcommittee began a thorough process of evaluation of the regulatory relationship between health care providers and suppliers and the Centers for Medicare and Medicaid Services (CMS). At the first public hearing that focused on bringing regulatory relief to Medicare providers, held on March 15, 2001, the Subcommittee received testimony from witnesses frustrated with a system that forces health care providers to spend their time and office resources on paperwork rather than patients.

The message delivered by health care providers in that first hearing was unanimous—doctors and hospitals, home health agencies and nursing homes all told the Subcommittee that they are overwhelmed. Instead of caring for patients, health care providers

testified that they spend too much time filling out unnecessary and confusing forms.

In addition, Medicare's current contracting represents an antiquated, inefficient, and closed system based on cozy relationships between the government, contractors and providers.

The Medicare contracting program is antiquated because contractors may not service the entire Medicare program, or particular functions within the program; rather Fiscal Intermediaries administer claims for facilities and carriers administer claims for all other providers. It has failed to keep pace with integrated delivery in the private sector.

Medicare's contracting program is inefficient because Medicare does not award contracts through competitive procedures, but rather on provider nomination.

Medicare's contracting program is closed. All but one of the contractors today have been with Medicare since the program's inception 36 years ago, and only insurers can provide contracting services.

C. LEGISLATIVE HISTORY

After the March 15 hearing, Chairman Nancy Johnson and Ranking Member Pete Stark wrote Secretary Thompson with a number of suggestions regarding regulatory improvements the Department could make using existing administrative authority. Many of those changes have already been adopted.

However, because many of the problems identified through the Subcommittee's work could not be corrected administratively, the Subcommittee began work in March on a legislative package. Through extensive collaboration with the provider community, the General Accounting Office and the Bush Administration, a draft bill was developed. The bill was responsive to issues raised by the Office of Inspector General in order to ensure that the package extends regulatory relief to providers while protecting taxpayers and beneficiaries from waste, fraud, and abuse. The bill was introduced on August 2 as H.R. 2768 and referred to the Committee on Ways and Means' Subcommittee on Health and the Committee on Energy and Commerce.

On September 25, the Subcommittee held a follow-up hearing on H.R. 2768 to elicit additional suggestions on the bill as introduced. Testimony was provided by CMS Administrator Tom Scully, the General Accounting Office and representatives of provider groups.

After approving Representative Johnson's amendment in the nature of a substitute, the Subcommittee on Health ordered favorably reported the bill on October 4, 2001 to the full Ways and Means Committee by voice vote with a quorum present with no additional amendments.

On October 11, after approving Chairman Thomas' amendment in the nature of a substitute, the full Committee on Ways and Means ordered favorably reported H.R. 2768 to the House of Representatives by voice vote with a quorum present. There were no additional amendments.

II. EXPLANATION OF PROVISIONS

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

Current Law.—No provision.

Explanation of Provision.—Except as otherwise specified, the provisions would amend or repeal a section or other provisions of the Social Security Act. 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 consolidation of other items related to Part A and Part B. Finally, the term, “supplier,” means a physician, practitioner, facility, or other nonprovider entity that furnishes Medicare items or services unless otherwise indicated.

Effective Date.—Upon enactment.

Reason for Change.—The Subcommittee is committed to extending needed regulatory relief to providers and suppliers while at the same time protecting taxpayers from waste, fraud and abuse.

Section 2. Issuance of regulations

(a) Consolidation of promulgation to once a month

Current Law.—The Secretary is required to issue 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 that determines 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 exception 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.

Explanation of Provision.—The Secretary would be required (1) to issue proposed or final regulation (including interim final regulation) only on one business day of the month unless publication on another date is necessary to comply with statutory requirements and (2) coordinate the issuance of new regulations relating to a category of provider or supplier based on an analysis of the collective

impact of the regulatory changes on such category. No later than 3 years after enactment, the Secretary would be required to report to Congress on the feasibility of issuing regulations only on one day in each calendar quarter.

Effective Date.—The provisions would apply to regulations issued 30 days after enactment.

Reason for Change.—The volume of Medicare regulations issued by CMS can be difficult for health care providers and suppliers, particularly small providers and suppliers, to monitor. By requiring periodicity on the release of regulations, providers and suppliers will be better able to keep informed of program changes.

The collective impact provision ensures that the Department will consider the overall impact of any changes it is making on categories of providers and suppliers. If the Department determines that many changes affecting a particular category of providers or suppliers are underway, the Department should consult with representatives of that category to determine whether providers and suppliers would be better able to make the systems changes needed to accommodate those changes if all the new regulations were released simultaneously or staggered. Because of the burden implementing multiple regulations simultaneously can cause, the Secretary needs to coordinate new regulations based on an analysis of the collective impact the regulatory changes will have on any given category of provider or supplier.

(b) Regular time line for publication of final rules

Current Law.—See above. The Secretary must publish in the Federal Register no less frequently than every 3 months, a list of all manual instructions, interpretative rules, statements of policy, and guidelines which are promulgated to carry out Medicare's law.

Explanation of Provision.—The Secretary, in consultation with the Director of the Office of Management and Budget, would establish and publish a regular time line for the publication of final regulations based on the previous publication of a proposed regulation or an interim final regulation. The time line may vary by regulation due to complexity, number and scope of comments received and other factors. The Secretary would be required to publish in the Federal Register any variations in the time line for publication of the final regulation. This notice of the different time line would need to: (1) be published no later than the end of the comment period for the proposed regulation and (2) include a brief explanation of the justification for such variation. If the regular time line established for an interim final regulation expires without promulgation of a final regulation (and associated public comment period), the interim final regulation would not remain in effect unless the Secretary publishes a notice of continuation that would include an explanation for not complying with the regular time line. The interim regulation's regular time line would be restarted on the date that the notice of continuation is published. The Secretary would be required to submit a report to Congress that describes and explains the instances where the final regulation was not published within the applicable time line.

Effective Date.—Upon enactment. The Secretary would be required to provide for a transition period for previously published interim final regulations.

Reason for Change.—Numerous regulations have been issued by CMS as interim final regulations and never finalized. This injects an element of uncertainty into the regulation in question, and it precludes the ability of CMS to incorporate changes based on comments received by interested parties into a final regulation. The provision ensures that proposed regulations will move through the process of finalization in a predictable and timely manner.

(c) *Limitation on new matter in final regulations*

Current Law.—No provision.

Explanation of Provision.—A provision in a final regulation that is not a logical outgrowth of the proposed regulation would be treated as a proposed regulation and would not take effect without a separate public comment period followed by publication as a final regulation.

Effective Date.—Upon enactment.

Reason for Change.—The provision ensures that interested parties will be given an opportunity to comment on issues addressed in regulations before they take effect. The Committee 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.

Section 3. Compliance with changes in regulations and policies

(a) *No retroactive application of substantive changes; time line for compliance with substantive changes after notice*

Current Law.—No provision.

Explanation of Provision.—A substantive change in Medicare regulations, manual instructions, interpretive rules, policy statements, or guidelines would not be applied retroactively to items or services furnished before the date it was issued, unless the Secretary determines that retroactive application would be necessary to comply with statutory requirements or would have a positive impact on beneficiaries or providers and suppliers. The substantive change would not be effective until at least 30 days after it is issued. No compliance action could be taken against a provider or supplier with respect to the change for items and services furnished before the effective date.

Effective Date.—Upon enactment.

Reason for Change.—This provision will ensure providers and suppliers will have sufficient time to make any changes to systems needed to comply with changes in regulations.

(b) *Reliance on guidance*

Current Law.—No provision.

Explanation of Provision.—If (1) a provider 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 and (3) the guidance is inaccurate, the provider or supplier would not be subject to any sanction including repayment or any penalty. This provision would not be construed to prevent repayment (or payment of penalties) to the extent that the overpayments result from a clerical or technical operational error. GAO is instructed to conduct a study on the feasibility and appropriateness of legally binding advisory opinions on appropriate interpretation and application of Medicare regulations.

Effective Date.—Upon enactment.

Reason for Change.—This provision will ensure that providers and suppliers who acted in good faith based on the information they received from their contractors will not be vulnerable to recovery if it turns out that the contractor was in error. Providers should be able to rely on the directions or guidance provided to them by their Medicare contractors, even if there is a technical or clerical error on the part of the contractor in developing or providing the direction or guidance. The protections of new section 9(b) are not available in the case of a technical or clerical error that is not incorporated into direction or guidance and therefore not relied upon by the provider in providing supplies or services. For example, a simple miscalculation in the payment of a claim that results in the wrong amount being sent to a provider would be recoverable.

Section 4. Increased flexibility in Medicare administration

(a) Consolidation and flexibility in Medicare administration

Current Law.—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 insurer 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 to improve or maintaining good performance as well. The Secretary may not require that carriers or intermediaries 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, reconsideration 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 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.

Explanation of Provision.—The legislation would add Section 1874A to the Social Security Act which would permit the Secretary to enter into contracts with any entity to serve as a Medicare administrative contractor. These contractors would perform, or secure the performance of (through subcontracting), some or all of the following tasks: determine payment amounts; making payments; educate and assist beneficiaries; consult and communicate with and assist providers and suppliers; and perform additional functions as necessary. 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 or supplier, or class of provider or supplier.

The Secretary would be required to use competitive procedures when entering into a Medicare administrative contract but would be able to renew a contract for up to five years without regard to statutory requirements concerning competitive contracting if the entity has exceeded specified performance standards. These standards would take into account performance, quality, price, and other factors. Functions would be able to be transferred among Medicare administrative contractors, consistent with these provisions. The Secretary would be required to (1) consider performance quality in such transfers; (2) provide incentives for the Medicare administrative contractors to provide efficient, high-quality services; and (3) develop performance standards with respect to each of the payment, provider service, and beneficiary service functions required of the contractors. With respect to developing the performance standards, the Secretary would be able to consult with providers, suppliers and organizations performing the contracting functions. The Secretary would be required to contract only with those entities that (1) will perform efficiently and effectively; (2) will meet standards for financial responsibility, legal authority and service quality among other pertinent matters; (3) will agree to furnish timely and necessary data; and (4) will maintain and provide access to necessary records and data. The Secretary retains his authority to cover the termination costs of current contractors.

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. As under current law, the Secretary would not be able to require existing or new contractors to match their data with Medicare data for the purposes of the 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 DME. An entity with a MIP contract would not be treated as a Medicare administrative contractor, solely by reason of the MIP contract. 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, reconsideration and exemption decisions.

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. It is the intent of Congress that the definition of a surety bond in this instance includes fidelity bonds and the Secretary has the authority to request fidelity bonds. The liability standard of "gross negligence or intent to defraud" is retained for individuals and designated officers but the agency and organization are now also liable under a "gross negligence or intent to defraud" standard; 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 an authorization from the certifying employee AND the authorization meets the internal control standards established by General Accounting Office (GAO). The Secretary would pay the Medicare administrative contractor, its employees, or their legal representatives for defending these contractors or employees in a civil action related to the performance of their contractual duties, if due care was exercised in the performance of such duties. These payments would be equal to the reasonable amount of legal expense incurred.

Effective Date.—See subsection (d).

Reason for Change.—Medicare's current contracting represents an antiquated, inefficient, and closed system based on cozy relationships between the government, contractors and providers.

The Medicare contracting program is antiquated because contractors may not provide service for the entire Medicare program, or particular functions within the program; rather Fiscal Intermediaries administer claims for facilities and carriers administer claims for all other providers. It has failed to keep pace with integrated claims administration practices in the private sector.

Medicare's contracting program is inefficient because Medicare does not award contracts through competitive procedures, but rather on provider nomination.

Medicare's contracting program is closed. All but one of the contractors today have been with Medicare since the program's incep-

tion 36 years ago, and only insurers can provide contracting services.

This provision permits greater flexibility in contracting for administrative services between the Secretary and the Medicare contractors (entities that process claims under part A and part B of the Medicare program), including the flexibility to separately contract for all or parts of the contractor functions. The Secretary also may contract with a wider range of entities, so that the most efficient and effective contractor can be selected.

These amendments require the Secretary to contract competitively at least once every five years for the administration of benefits under parts A and B. In conjunction with the elimination of cost contracts, it is intended to create incentives for improved service to beneficiaries and to providers of services and suppliers. Finally, it establishes a liability standard of gross negligence or intent to defraud for the agency or organization, to eliminate a statutory ambiguity that appeared to extend immunity to that entity for fraudulent payments certified and disbursed to Medicare Part A providers.

(b) Conforming amendments to section 1816 (relating to fiscal intermediaries)

Current Law.—Section 1816 of the Social Security Act establishes the provider nomination process, the contracting specifications, and performance standards for fiscal intermediaries that currently contract with Medicare to process claims and perform other related administrative activities for institutional providers.

Explanation of Provision.—The provisions establish that the activities of fiscal intermediaries in administering Medicare would be conducted through contracts with Medicare administrative contractors as set forth in subsection (a). 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.

Effective Date.—See subsection (d).

Reason for Change.—These amendments provide a basis for a unified contracting system for the administration of parts A and B, identical to the recent Congressionally mandated structure of the Medicare Integrity Program contractors. Consolidation of contracting duties as set forth in this legislation does not constitute consolidation of the Hospital Insurance and Medical Supplementary Insurance Trust Funds, or reflect any position on that issue. In addition, the elimination of provider nomination, which has been rarely allowed in recent years, is essential for bringing full and open competition into the contracting functions of the Medicare program.

(c) Conforming amendments to section 1842 (relating to carriers)

Current Law.—Section 1842 of the Social Security Act establishes that carriers will be used to administer certain Medicare benefits as well as the contracting requirements and certain performance standards for those activities.

Explanation of Provision.—The provisions would establish that the activities of carriers administering Medicare would be conducted through contracts with Medicare administrative contractors as set forth in subsection (a). Certain instructions including those pertaining to nursing facilities' 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 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. Certain annual reporting requirements concerning the contractor's overpayment recovery efforts would be retained.

Effective Date.—See subsection (d).

Reason for Change.—The provision establishes a basis for a unified contracting system, identical to the structure implemented for the Medicare Integrity Program contractors. It is important to note, however, that consolidation of contracting duties as set forth in this legislation does not constitute consolidation of the Hospital Insurance and Medical Supplementary Insurance Trust Funds, or reflect any position on that issue. In addition, the Secretary would have the flexibility to choose the best contractor(s) to provide telephone information on suppliers which is intended to reduce administrative costs and improve quality.

(d) *Effective date; transition rule*

Current Law.—No provision.

Explanation of Provision.—Except as otherwise provided in this subsection, the provisions in this section would be effective October 1, 2003. The Secretary would be authorized to take necessary actions prior to that date in order to implement these amendments on a timely basis to transition from the contracts established under sections 1816 and 1842 of the Social Security Act to those established under the new section 1874A created by this legislation. The transition would be consistent with the requirement that the administrative contracts be competitively bid by October 1, 2008. The requirement that MIP contracts be awarded on a competitive basis would continue to apply and would not be affected by the provisions in this section. The MIP contracting exception that allows agreements according to current law would be deemed to be a contract established under the new authority of 1874A and would continue existing activities. The Secretary has the authority to recognize the appropriate termination costs of current cost contracts in the transition from current cost contracts to competitively bid contracts.

Reason for Change.—The provision provides for the appropriate transition between the current contracting system and these amendments.

(e) *References*

Current Law.—No provision.

Explanation of Provision.—After this section becomes effective, any reference to fiscal intermediary or carrier would be considered a reference to the appropriate Medicare administrative contractor.

Reason for Change.—These amendments are necessary to conform existing law to the new structure.

Section 5. Provider education and technical assistance

(a) Coordination of education funding

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.

Explanation of Provision.—The provision 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) to submit an evaluation to Congress on actions taken to coordinate the funding of provider education.

Effective Date.—Upon enactment with report due to Congress no later than October 1, 2002.

Reason for Change.—This provision is intended to ensure that federal spending on provider education is coordinated and used as efficiently as possible to maximize the value obtained from the investment. It is not intended to change the proportion or Medicare Integrity Program funds spent on provider education.

(b) Incentives to improve contractor performance

Current Law.—No specific statutory provision. Since FY1996, as part of the audit required by the Chief Financial Officers Act, an estimate of improper payments in Medicare fee-for-service has been established annually. As a recent initiative, CMS is implementing a comprehensive error rate testing program to produce national, contractor specific, benefit category specific and provider specific paid claim error rates.

Explanation of Provision.—The Secretary would be required to (1) develop a methodology, in consultation with representatives of providers and suppliers, to measure the specific claims payment error rates at each Medicare administrative contractor; and (2) identify best practices developed at each contractor for educating providers and suppliers. The Secretary would be required to report to Congress on (1) the use of the claims error rate methodology in assessing the effectiveness of contractors’ provider education and outreach programs and (2) whether methodology should be used as the basis of bonuses for contractors. The report shall also include an analysis of the sources of identified errors and potential changes in systems of contractors and rules of the Secretary that could reduce claims error rates.

Effective Date.—Methodology is to be implemented and report is due to Congress by October 1, 2003.

Reason for Change.—This provision would ensure that the Department monitors contractor level performance as it relates to claims payment error rates, and it would identify best practices for

provider education—all with the goal of reducing payment errors and helping providers and suppliers better comply with program requirements.

(c) Provision of access to and prompt responses from Medicare administrative contractors

Current Law.—No specific statutory provision. 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.

Explanation of Provision.—Each Medicare administrative contractor would be required to (1) respond clearly, concisely and accurately to billing and cost reporting questions; (2) maintain a toll-free telephone number for such inquiries; (3) maintain a system for identifying, and disclosing on request, which employee provided the information; and (4) monitor the quality of the information provided. The Secretary would be required, in consultation with provider organizations, to establish performance standards with respect to telephone inquiries from providers and suppliers.

Effective Date.—October 1, 2003.

Reason for Change.—This provision is intended to improve contractor accountability to make contractors more responsive to providers and suppliers, and to increase the accuracy and reliability of the information provided in response to the questions received.

(d) Improved provider education and training

Current Law.—In FY2000, \$54.8 million was spent on provider education and training activities: about \$43 million from the program management appropriation and about \$12 million came from the provider education and training component of MIP. In FY2001, about \$57.3 million was budgeted for these activities.

Explanation of Provision.—The provision would authorize an increased \$10 million appropriation from Medicare Trust Funds (as appropriate from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) in FY2003 and FY2004 to increase Medicare contractors' billing, coding and other provider training activities. Medicare administrative contractors would be required to conduct education and training activities for small providers of services or suppliers, that is, institutional providers with less than 25 full-time equivalents (FTEs) or suppliers with less than 10 FTEs.

Effective Date.—October 1, 2002.

Reason for Change.—This provision acknowledges that contractors are being instructed to significantly improve their provider education and training efforts, and accordingly authorizes new funds to be available for those purposes.

(e) Requirement to maintain Internet sites

Current Law.—No provision.

Explanation of Provision.—The Secretary and each Medicare administrative contractor would be required to maintain an Internet site which provides easily accessible answers to frequently asked questions as well as other published materials of the contractor.

Effective Date.—October 1, 2002.

Reason for Change.—This provision will facilitate greater ease of provider and supplier access to information provided by Medicare's contractors.

(f) Additional provider education provisions

Current Law.—No provision.

Explanation of Provision.—A Medicare contractor would not be able to use attendance records at educational programs or information gathered during these programs to select or track providers or suppliers for audit or prepayment review. Nothing in the proposed legislation would require Medicare administrative contractors to disclose claims processing screens (computer edits that trigger medical review) or information that would compromise pending law enforcement activities or law enforcement-related audits.

Effective Date.—Upon enactment.

Reason for Change.—This provision addresses a concern raised by providers and suppliers that their participation in educational forums has been used to trigger audits. Participation in educational forums should be encouraged not discouraged.

Section 6. Small provider technical assistance demonstration program

Current Law.—No provision.

Explanation of Provision.—The Secretary would be required to establish a demonstration program that offers technical assistance, upon request, to small providers or suppliers (institutional providers with less than 25 full-time equivalents (FTEs) or suppliers with less than 10 FTEs.) Technical assistance would include direct in-person examination of billing systems and internal controls by qualified entities, such as peer review organizations or other entities. The technical assistance would also make available information and assistance regarding policies and procedures under Medicare, including coding and reimbursement. In awarding these contracts, the Secretary would be required to consider any prior investigations of the entity's work by the Office of the Inspector General (OIG) in HHS or the GAO. Participating providers and suppliers would be required to pay an amount estimated and disclosed in advance that would equal 25% of the cost of the technical assistance they received. Absent indications of fraud, errors found in the review would not be subject to recovery if the problem is corrected within 30 days of the on-site visit and remains corrected for an appropriate period. GAO, in consultation with the OIG, would be required to evaluate and recommend continuation of the demonstration project no later than two years after its implementation. The evaluation would include a determination of whether claims error rates were reduced for providers and suppliers who participated in the program. The evaluation would also study whether improper payments were made as a result of the demonstration. The provision would authorize \$1 million in FY2003 and \$6 million in

FY2004 of appropriations from the Medicare Trust Funds to carry out demonstration project.

Effective Date.—Upon enactment.

Reason for Change.—Many large providers and suppliers have contracts with private consulting firms to help them navigate their interactions with the Medicare program. This type of assistance can be prohibitively expensive for small providers and suppliers—but they too are required to comply with complex program rules and regulations. This provision creates a new demonstration program to facilitate small provider and supplier access to expert technical assistance. The demonstration will also test whether encouraging technical assistance on the front end to help providers and suppliers play by the rules can save the program money in the longer term by promoting greater program compliance.

Section 7. Medicare Provider Ombudsman; Medicare Beneficiary Ombudsman

Current Law.—No statutory provisions address Medicare Provider or Beneficiary Ombudsman programs. The Secretary is required to prepare and distribute an annual notice explaining Medicare benefits and limitations to coverage to Medicare beneficiaries. The Secretary is also required to provide information via a toll-free telephone number.

Explanation of Provision.—The Secretary would be required to appoint a Medicare Provider Ombudsman to (1) to resolve unclear guidance and provide confidential assistance to providers and suppliers regarding complaints or questions about the Medicare program, including peer review and administrative requirements; and (2) recommend changes to improve program administration.

The Secretary would also be required to appoint an internal Medicare Beneficiary Ombudsman from individuals with health care expertise and advocacy. The ombudsman would (1) receive complaints, grievances, and requests for information from Medicare beneficiaries; (2) provide assistance with respect to those complaints, grievances and requests, including assistance to beneficiaries who appeal claims determinations or those affected by the decisions of Medicare+Choice organizations to leave Medicare; and (3) submit an annual report to Congress and the Secretary describing activities and recommending changes to improve program administration from a beneficiary perspective.

The provision would authorize appropriations of necessary sums in FY2002 and subsequently from the appropriate Medicare Trust Funds for these Ombudsman programs.

Finally, the Secretary would be required to establish a toll-free number (1-800-MEDICARE) to triage individuals with questions or seeking help to the appropriate individuals or entities. The triage would occur with no charge. This toll-free number would be the only general information and assistance number listed in the Medicare handbook and annual notice provided to Medicare beneficiaries, replacing phone numbers for Medicare contractors. However, assistance numbers that are not Medicare contractors would continue to be listed separately, such as numbers for State Health Insurance Counseling and Assistance Programs.

Effective Date.—Upon enactment.

Reason for Change.—Beneficiaries and providers are currently confronted with a morass of bureaucracy and regulation, with no clear individual to assist them. The beneficiary handbook currently provides many pages of phone numbers, which can be very confusing for beneficiaries, rather than a single number that then triage beneficiaries to the appropriate person or entity. The provisions in this section are intended to help providers and beneficiaries navigate Medicare’s complicated rules and regulations.

Section 8. Provider appeals

(a) Medicare administrative law judges

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 was amended by Benefits Improvement and Protection Act of 2000 (BIPA) in its entirety, but 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 through a series of administrative appeals and then into federal district court if the amounts of disputed claims in question meet certain thresholds at each step of the appeals process. A hearing by an administrative law judge (ALJ) in the Social Security Administration (SSA) is one component of the administrative appeals process.

Explanation of Provision.—By October 1, 2003, the Commissioner of SSA and the Secretary would be required to develop and implement a plan to transfer the functions of the ALJs responsible for hearing Medicare cases from SSA to Health and Human Services. This plan would include recommendations on the number of judges and support staff required to adjudicate cases on a timely basis and funding needed for FY2004 and subsequently. The Secretary of HHS is required to submit to the Committee on Ways and Means of the House of Representatives, the Committee on Finance of the Senate, and the Comptroller General the terms of the plan by July 1, 2003. By September 1 of that year, GAO has to report back to the Committees with an evaluation of the transfer plan. The provision would authorize increased appropriations, in addition to amounts otherwise appropriated, from the appropriate Medicare Trust Fund of \$5 million in FY2003 and as necessary in subsequent years in order to increase the number of administrative law judges and to improve education and training programs for judges and their staff in carrying out their Medicare activities. Nothing in this provision would be construed to affect the independence of ALJs in carrying out their responsibilities for adjudicating cases.

Effective Date.—Upon enactment, with the mandated report concerning ALJ transfer due by October 1, 2003.

Reason for Change.—The Office of Inspector General has identified moving the functions of the Medicare Administrative Law Judges to the Department of Health and Human Services as an important priority in improving the appeals system. This provision makes that transition and increases the emphasis on providing training Administrative Law Judges and their staffs to increase their expertise in Medicare’s rules and regulations. The SSA Commissioner and the Secretary are instructed to work together on the

transition plans in order to assure that the transition does not adversely affect the SSA ALJ appeals system.

(b) Process for expedited access to judicial review

Current Law.—Section 1869 (as modified by BIPA but not yet implemented) provides for expedited proceedings. Under BIPA provisions, an expedited determination is available to a beneficiary who has received notice: (1) that a provider plans to terminate services and a physician certifies that failure to continue services is likely to place the beneficiary's health at risk; or (2) the provider plans to discharge the beneficiary. In instances where the moving party alleges that no material issues of fact are in dispute, the Secretary will make an expedited determination as to whether any such facts are in dispute and, if not, will render a decision expeditiously.

Explanation of Provision.—The Secretary would be required to establish a process where a provider or supplier of a service or a beneficiary who has filed an appeal may obtain 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 it does not have the authority over law or regulation in question and where material facts are not in dispute. If so decided, the appellant would be able to bring a civil court action if the civil action is filed within 60 days. The venue for judicial review would be the U.S. District Court where the appellant is located, or where the greatest number of appellants are located, or in the district court in DC. The amount in controversy would be subject to annual interest awarded to the prevailing party by the reviewing court. The provision for expedited access to judicial review would apply to a provider's appeal concerning program participation.

A review panel would be an administrative law judge (ALJ), the Departmental Appeals Board (DAB), a Qualified Independent Contractor (QIC) or other designated entity. A decision by the review panel would be a final decision and would not be subject to review by the Secretary. The appellant would be able to request this determination only once with respect to a particular question of law or regulation.

These expedited access to judicial review provisions will also apply to application of termination proceedings, relating to survey and certification determinations, under 1866(h).

Effective Date.—Applies to appeals filed on or after October 1, 2002.

Reason for Change.—This provision ensures that if a review board certifies that there are no material facts in dispute and that the appeals process does not have authority to resolve the question at issue, the provider, supplier, or beneficiary may take their case to court in an expedited manner. This will facilitate more prompt resolution of challenges to the underlying validity of CMS regulations and determinations.

(c) Requiring full and early presentation of evidence

Current Law.—No provision.

Explanation of Provision.—A provider of services or supplier would not be able to introduce evidence that was not presented at

reconsideration conducted by the QIC unless a good cause precluded its introduction at or before that reconsideration.

Effective Date.—On or before October 1, 2002.

Reason for Change.—The Office of Inspector General identified this change as a priority to promote more expeditious resolution of appeals of denied claims. This provision requires prompt introduction of evidence relevant to a provider appeal.

Section 9. Recovery of overpayments and prepayment review; enrollment of providers

(a) Recovery of overpayments and prepayment review

Current Law.—No specific statutory provisions address the payment plans, consent settlements, prepayment, or post-payment actions. Section 1833(j) of the Social Security Act provides that interest accrues on under-payments or overpayments starting 30 days of the date of the final determination of the accurate payment amount.

Explanation of Provision.—Subject to certain qualifications, in circumstances where refund of an overpayment within 30 days would constitute a hardship, providers and suppliers would be allowed to repay overpayment amounts over a period of up to three years when their overpayment obligation exceeds a 10% threshold of their annual payments from Medicare. The Secretary would be able to determine cases of extreme hardship where a repayment period of up to five years could be established. Interest would accrue on the balance through the repayment period. The Secretary would be required to establish the way that newly-participating providers and suppliers could qualify for a repayment plan under this hardship provision. Previous overpayment amounts already included in an ongoing repayment plans would not be included in the calculation of the hardship threshold. The Secretary would be allowed to seek immediate collection if payments are not made as scheduled. Exceptions to this provision would be permitted in cases where bankruptcy may be declared or fraud or abuse is suspected.

For providers and suppliers who appeal an overpayment determination, the Secretary would be prevented from recovering an overpayment until the date of the qualified independent contractor decision. The Secretary would be required (1) to collect interest that accrues starting on the date of the overpayment notice if the appeal decision is against the provider, physician, practitioner or supplier and (2) to pay the recouped amount plus interest if the appeal decision is subsequently reversed.

Medicare contractors, both MIP and Medicare administrative contractors, would be able to conduct random prepayment reviews only in order to develop contractor-wide or program-wide claims payment error rates. These random prepayment reviews would be developed in consultation with providers and suppliers. Contractors would be able to deny payments for claims subject to the prepayment reviews.

Medicare contractors would not be able to use extrapolation to determine overpayment amounts unless a sustained or high level of payment error exists (as defined by the Secretary through regulations) or a documented educational intervention did not correct the payment error.

Medicare contractors would be permitted to periodically request records or documentation for a limited sample of claims from providers or suppliers who had been overpaid to ensure that the previous practices have been corrected.

The Secretary would be able to use a consent settlement to resolve a projected overpayment. As part of the process, the Secretary would be required to (1) communicate in a non-threatening manner to a provider, or supplier that, based on a preliminary analysis of medical records, an overpayment may exist; (2) provide 45 days where additional information may be submitted by the provider and supplier regarding these medical records; (3) after considering the additional information, provide notice and explanation of any remaining overpayment determination; and (4) offer the opportunity for a statistically valid random sample (which would not waive appeal rights) or a consent settlement (based on a smaller sample with a waiver of appeal rights) to resolve the overpayment amounts.

Medicare contractors would not be able to implement non-random prepayment review based on initial identification of an improper billing practice by the provider or supplier unless a sustained or high level of payment error exists. The Secretary would be required to issue regulations concerning the timing and termination of prepayment reviews as well as the different circumstances that would affect the duration of these reviews.

Medicare contractors would be required to provide a written notice of the intent to conduct a post-payment audit to providers, and suppliers selected as audit candidates. During the exit conference between the provider or supplier and the contractor, the contractor would be required to provide a full review and understandable explanation of the findings to those who have been audited. This full review (1) would permit the development of an appropriate corrective action plan; (2) would provide information on appeal rights; (3) would provide for an opportunity to supply additional information to the contractor; and (4) take into account that additional information which was provided on a timely basis. A notice of audit or explanation of findings would not be required if law enforcement activities or audits would be compromised.

The Secretary would be required to establish a process where classes of providers and suppliers are notified that their Medicare contractor has identified specific billing codes that may be over-utilized.

Effective Date.—Upon enactment.

Reason for Change.—These provisions build greater consistency and predictability into Medicare's rules for recovery of overpayments and prepayment review, while protecting program integrity.

(b) Enrollment process for providers of services and suppliers

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 for 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 suppliers. Sections 1128(a) and (b) of the Act provide for

the exclusion of certain individuals or entities because of the conviction of crimes related to their participation in Medicare; Section 1128(f) provides for hearing and judicial review for exclusions. In 1999, the Health Care Financing Administration (HCFA—now the Centers for Medicare and Medicaid Services or CMS) published a proposed regulation that would revise existing Medicare Part B administrative appeals procedures and extend them to all suppliers not currently covered.

Explanation of Provision.—The Secretary would be required to establish by regulation an enrollment process which provides an appeal mechanism with prompt deadlines for those providers and suppliers whose applications to participate in Medicare are denied.

Effective Date.—Within 6 months of enactment.

Reason for Change.—This provision gives providers and suppliers an opportunity to appeal denials of their applications to participate in the Medicare program.

(c) *Process for correction of minor errors and omissions on claims without pursuing appeals process*

Current Law.—No provision.

Explanation of Provision.—The Secretary would be required to develop, in consultation with appropriate Medicare contractors and health care associations, a process where minor claims errors can be corrected and resubmitted without appealing the claims denial.

Effective Date.—Upon enactment.

Reason for Change.—Many of the providers and suppliers who testified before the Subcommittee or contacted members directly emphasized the need to create a process in which they could correct claims that were denied because they were incomplete or contained minor errors without having to pursue a formal appeal. This provision instructs the Secretary to create such a process, which will alleviate pressure on the appeals system. The Subcommittee would be concerned, however, if this process were to become an incentive for providers to knowingly or negligently submit incomplete information.

The Committee intends that the process for correction of minor errors and omissions on claims cover both the submission of prepayment and post-payment review claims. For example, if in the case of a home health claim, the physician has signed the plan of care and/or physician's order but has not dated it, the claim shall be returned to the home health agency and may be resubmitted by the home health agency with any incomplete or missing information without having to appeal the claim.

Section 10. Beneficiary outreach demonstration program

Current Law.—No provision.

Explanation of Provision.—The Secretary would be required 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 the offices 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 bene-

fiary utilization, beneficiary satisfaction, and cost-effectiveness and (2) recommend whether the demonstration should be established on a permanent basis.

Effective Date.—Upon enactment.

Reason for Change.—This provision makes Medicare experts available in six Social Security Administration offices to assist beneficiaries and answer their questions. The demonstration will test whether such outsourced Medicare specialists improve beneficiary utilization and understanding of the program, and beneficiary satisfaction.

Section 11. Policy development regarding evaluation and management (E&M) documentation guidelines

Current Law.—No provision.

Explanation of Provision.—The Secretary would not be permitted to implement any documentation guidelines for evaluation and management (E&M) physician services unless the guidelines (1) are developed in collaboration with practicing physicians 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 the pilot projects to test modifications to the codes; (4) are found to meet the desired objectives; and (5) are preceded by appropriate outreach and education of the physician community. The Secretary would make changes to existing E&M guidelines to reduce paperwork burdens on physicians. The Secretary would be required to modify E&M guidelines to (1) enhance clinically relevant documentation; (2) decrease the 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 be (1) conducted in consultation with practicing physicians; (2) be of sufficient length to educate physicians and contractors on E&M guidelines and (3) allow for an assessment of E&M guidelines and their use. A range of different projects would be established, including a peer review method by physicians as well as projects in a rural area, outside rural areas as well as in a teaching setting and non-teaching setting. One of the pilot programs would focus on an alternative method to detailed guidelines, based on physician documentation of face to face encounter time with a patient. 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. The Secretary, in consultation with practicing physicians, would be required to evaluate the development of alternative E&M documentation systems with respect to administrative simplification requirements and report results of the study to Congress. The Medicare Payment Advisory Commission would conduct an analysis of the results of this study and submit a report to Congress.

The Secretary would be required to conduct a study of the appropriate coding of extended office visits where no diagnosis is made and submit a report with recommendations to Congress.

Effective Date.—Upon enactment.

Reason for Change.—This provision is designed to promote greater consultation with practicing physicians with regard to the com-

plicated evaluation and management and coding requirements governing Medicare payment for physician services.

Section 12. Improvement in oversight of technology and coverage

(a) Improved coordination between FDA and CMS on coverage of breakthrough medical devices

Current Law.—No provision.

Explanation of Provision.—At the request of the applicant and to the extent feasible and upon request, the Secretary would be required to coordinate and share appropriate information under reviews of Medicare coverage decisions and Food and Drug Administration's (FDA) reviews of applications for pre-market approval of class III medical devices under Section 515 of the Federal Food, Drug, and Cosmetic Act. The Secretary would be required to submit a report on the implementation plan to lessen the delay between FDA's pre-market approval and Medicare's coding and coverage decisions to the appropriate Congressional committees. This provision would not change Medicare's coverage nor FDA's pre-market approval criteria.

Effective Date.—Upon enactment with report to Congress on implementation plan due no later than six months after enactment.

Reason for Change.—After the FDA pre-market approval, the Medicare program does a second evaluation of breakthrough technologies to determine effectiveness and cost of those technologies compared to existing technologies. The review is necessary and appropriate, but it can take months between FDA approval and the availability of new technology for Medicare beneficiaries. By coordinating FDA and CMS approval of breakthrough medical devices, where feasible, this provision is intended to facilitate a more efficient process for the coverage of certain new technology by the Medicare program.

(b) Council for Technology and Innovation

Current Law.—No provision.

Explanation of Provision.—The Secretary is required to establish a Council for Technology and Innovation within the Centers for Medicare and Medicaid Services (CMS) and appoint or designate a Executive Coordinator for Technology and Innovation. The Council would be composed of senior CMS staff chaired by the Executive Coordinator who reports to the CMS administrator. The Council shall coordinate Medicare's coverage, coding, and payment processes as well as information exchange with other entities with respect to new technologies and procedures, including drug therapies.

Effective Date.—Upon enactment.

Reason for Change.—CMS personnel responsible for coverage, coding and payment of medical innovation are often not well coordinated. This provision creates a focal point for technology and innovation within the Centers for Medicare and Medicaid Services by creating a Council to coordinate across the different Centers and Offices with responsibilities in this area. The Executive Coordinator also provides a single point of contact for outside groups, similar to recent initiatives launched by the Secretary for specific issues and types of providers.

(c) GAO study on improvements in external data collection for use in the Medicare inpatient payment system

Current Law.—No provision.

Explanation of Provision.—GAO would be required to conduct a study which analyzes how external data can be collected for use in computing Medicare's inpatient hospital payments. The study may include an evaluation of the feasibility and appropriateness of using quarterly samples or special surveys among other methods. The study would include an analysis of whether other agencies, such as the Bureau of Labor Statistics in the Department of Commerce, are best suited to collect this information.

Effective Date.—Report is due no later than October 1, 2002.

(d) Application of OSHA Blood Borne Pathogens standards to certain hospitals

Current Law.—No provision.

Explanation of Provision.—Public hospitals that are not otherwise subject to the Occupational Safety and Health Act of 1970 would be required to comply with the Blood Borne Pathogens standard under section 1910.1030 of title 29 of the Code of Federal Regulations. A hospital that fails to comply with the requirement would be subject to a civil monetary penalty, but would not be terminated from participating in Medicare.

Effective Date.—Applies to hospitals as of July 1, 2002.

Reason for Change.—Last year, Congress enacted legislation that requires hospitals to utilize safe needles. However, that legislation only applies to non-government hospitals. Twenty-four states have similar requirements on public hospitals. This provision would protect the health and safety of health care workers in those facilities by requiring public hospitals in the other 26 states and the District of Columbia to comply with this important standard.

(e) IOM study on local coverage determinations

Current Law.—No provision.

Explanation of Provision.—The Secretary would be required to arrange for a study by the Institute of Medicine (IOM) that would examine the capabilities and information available to establish Medicare's local coverage determinations. The study would examine: (1) the consistency of definitions used in the determinations; (2) the extent to which the determinations are based on evidence; (3) the advantages and disadvantages of local decision making; (4) whether, in the absence of adequate data, determinations to cover experimental items or services are made in order to collect data; (5) the advantages and disadvantages of maintaining local medicare contractor advisory committees.

Effective Date.—The IOM study would be due to the Secretary no later than three years after enactment when it would be promptly transmitted to Congress.

(f) Methods for determining payment basis for new lab tests

Current Law.—No provision.

Explanation of Provision.—The Secretary would be required to establish by regulation procedures for determining the basis for any new clinical diagnostic laboratory test. The Secretary must

make information available to the public on the methodology and data.

Effective Date.—January 1, 2003.

Reason for Change.—The Secretary of Health and Human Services is required to establish by regulation an open process for any clinical diagnostic laboratory test. Under the regulations, the Secretary shall develop criteria for use in determining whether a laboratory test should be established through gap-filling or cross-walking to an existing code. When existing services are not sufficient and gap filling must be used, the criteria shall explain the basis of the data, the collection of the data, and the methodology for computing the rate.

The intent of Congress is to open the process to allow CMS to have access to information from beneficiaries, physicians, health care experts and laboratories. Using the information it receives through this new process, CMS shall develop and make available to the public the information used to arrive at a final determination. The information will include the rationale for each such determination, the data on which the determination is based, and responses to public comments.

Section 13. Miscellaneous provisions

(a) Treatment of hospitals for certain services under the Medicare Secondary Payor (MSP) provisions

Current Law.—In certain instances when a beneficiary has other insurance coverage, Medicare becomes the secondary insurance. Medicare Secondary Payor is the Medicare program's process for coordination of benefits with other insurers. Section 1862(b)(6) of the Social Security Act requires an entity furnishing a Part B service to obtain information from the beneficiary on whether other insurance coverage is available.

Explanation of Provision.—The Secretary would not require a hospital or a critical access hospital to ask questions or obtain information relating to the Medicare secondary payor provisions in the case of reference laboratory services if the same requirements are not imposed upon those provided by an independent laboratory. Reference laboratory services would be those clinical laboratory diagnostic tests and interpretations of same that are furnished without a face-to-face encounter between the beneficiary and the hospital where the hospital submits a claim for the services.

Effective Date.—Upon enactment.

Reason for Change.—Hospitals would not have to directly contact each beneficiary on their retirement date, black lung status and other insurance information for reference laboratory services. While current law provisions for a claim containing valid insurance information are maintained, this provision is intended to reduce the amount of paperwork and regulatory burden related to the provision of these reference laboratory services by hospital-based entities.

(b) Clarification of prudent layperson test for emergency services under the Medicare fee-for-service program

Current Law.—Medicare requires participating hospitals that operate an emergency room to provide necessary screening and sta-

bilization services to a patient in order to determine whether an emergency medical situation exists prior to asking about insurance status of the patient.

Explanation of Provision.—Services that are provided by a hospital or a critical access hospital to a Medicare beneficiary who is not enrolled in Medicare+Choice plans in order to evaluate or stabilize an emergency medical condition that meets the application of the prudent layperson rule are deemed to be reasonable and necessary covered services.

Effective Date.—Effective for items or services furnished on or after January 1, 2002.

Reason for Change.—This change is intended to clarify that services provided by hospitals under the Federal mandate on the provision of emergency services to assure the health and safety of Medicare beneficiaries are covered by the Medicare fee-for-service program. It will eliminate regulatory burden by eliminating the necessity for the hospital to provide additional documentation or to appeal the denial of services provided under the prudent layperson standard. It is not intended to eliminate the section flexibility in a broader policy.

(c) Submission of overdue reports on payment and utilization of outpatient therapy services

Current Law.—Congress required the Secretary to submit a report by January 1, 2001 on the establishment of a mechanism for assuring appropriate utilization of outpatient therapy services. The Secretary was also required to conduct a study on the utilization of therapy services by June 30, 2001.

Explanation of Provision.—The moratoria delaying annual outpatient therapy caps imposed by the Balanced Budget Act of 1997 will expire on October 1, 2002. The Committee believes that the reimbursement policy for outpatient therapy services should be based on a policy that is not arbitrary but protects the program from the provision of inappropriate services. The Secretary is urged to submit the required reports to Congress immediately so that Congress can review any alternative policies on this issue as soon as possible.

Effective Date.—Upon enactment.

(d) Authorizing use of arrangements with other hospice programs to provide core hospice services in certain circumstances

Current Law.—Hospice programs are not permitted to use services provided under arrangement rather than to deliver hospice services. Services provided under arrangement are permitted for Part A and Part B hospital services as well as skilled nursing services. However, the originating hospital or skilled nursing facility is required to bill for the service and be responsible for the quality of care delivered by the subcontractor.

Explanation of Provision.—Hospice programs may enter into arrangements with another certified hospice program to provide services. The provision for under arrangement services is limited to extraordinary or non-routine circumstances, such as unanticipated periods of staffing shortages. The originating hospice program con-

tinues to bear the legal responsibility for billing and maintaining quality of care.

Effective Date.—Upon enactment.

Reason for Change.—Hospice programs would be allowed to use personnel from other hospice programs to provide services to hospice patients. The program is given the flexibility so that a hospice program could continue to serve a patient if he or she was temporarily out of the area due to travel. Otherwise, the provision of the care to the patient might be delayed by the paperwork and requirements in starting up a new service at another agency. It is the intent of Congress that the originating hospice maintains control over the billing and quality of care.

III. VOTES

In compliance with clause 3(b) of rule XIII of the Rules of the House of Representatives, the following statements are made concerning the votes of the Committee on Ways and Means in its consideration of H.R. 2768.

MOTION TO REPORT THE BILL

H.R. 2768 was approved by voice vote with a quorum present

VOTES ON AMENDMENTS

Chairman Thomas' amendment in the nature of a substitute was approved by voice vote with a quorum present.

IV. BUDGET EFFECTS OF THE BILL

A. COMMITTEE ESTIMATE OF BUDGETARY EFFECTS

In compliance with clause 3(d)(2) of rule XIII of the Rules of the House of Representatives, the following statement is made:

The Committee agrees with the estimate prepared by the Congressional Budget Office (CBO) which is included below.

B. STATEMENT REGARDING NEW BUDGET AUTHORITY AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee states that the Committee bill results in no increase in federal direct spending.

C. COST ESTIMATE PREPARED BY THE CONGRESSIONAL BUDGET OFFICE

In compliance with clause 3(c)(3) of rule XIII of the Rules of the House of Representatives requiring a cost estimate prepared by the Congressional Budget Office (CBO), the following report prepared by CBO is provided.

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, November 5, 2001.

Hon. WILLIAM M. THOMAS,
*Chairman, Committee on Ways and Means,
Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 2768, 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 M. LIEBERMAN
(For Dan L. Crippen, Director).

Enclosure.

H.R. 2768—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, and would place new requirements on those entities. It would require the Secretary of HHS to conduct several demonstrations, and would require the completion of several studies and reports.

Assuming the appropriation of the necessary funds, CBO estimates that implementing H.R. 2768 would cost \$41 million in 2002 and \$548 million over the 2002–2006 period.

The procedural changes required by H.R. 2768 would affect spending for services covered by Medicare, which is direct spending. However, many of the bill's requirements codify existing practices, while the other requirements would cause minor increases or decreases in spending for covered services. CBO estimates that the changes in direct spending would be insignificant. Because the bill would affect direct spending, pay-as-you-go procedures would apply.

H.R. 2768 contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA). The requirement for public hospitals participating in the Medicare program to comply with the bloodborne pathogens standard promulgated by the Occupational Safety and Health Administration (OSHA) would have cost implications for state and local governments. However, those requirements would be conditions of participating in a voluntary federal program and thus would not be intergovernmental mandates as defined in UMRA. H.R. 2768 contains no private-sector mandates as defined in UMRA.

Estimated Cost to the Federal Government: For this estimate, CBO assumes that the legislation would be enacted this fall and

that estimated amounts would be appropriated each year. The costs of this legislation fall within budget function 570 (Medicare).

Basis of estimate: Table 1 shows the estimated authorization levels and outlays for Medicare administrative expenses under current law and under H.R. 2768. Assuming appropriation of the estimated amounts, CBO estimates that enacting H.R. 2768 would cost \$41 million in 2002 and \$548 million over the 2002–2006 period.

TABLE 1.—ESTIMATED BUDGET IMPACT OF H.R. 2768

	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	3,267	3,464	3,631	3,757	3,913	4,074
Proposed changes:						
Estimated authorization level	0	46	125	134	126	130
Estimated outlays	0	41	116	133	128	129
Spending for Medicare administrative costs under H.R. 2768:						
Estimated authorization level	3,352	3,546	3,771	3,931	4,081	4,248
Estimated outlays	3,267	3,505	3,747	3,890	4,041	4,203

¹ Budget authority for 2001 is the amount appropriated for that year.

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 both the method by which CMS enters into contracts and the activities required of contractors. CBO expects that these provisions would increase the cost of administering contracts, the total amount CMS spends on contracts, and spending by contractors on the education of providers about Medicare billing practices. We estimate the cost of implementing these provisions would be \$14 million in 2002 and \$336 million during the 2002–2006 period.

H.R. 2768 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. 2768 would require CMS to competitively bid contracts with fiscal intermediaries and carriers at least every five years. CBO expects that an additional 3–5 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.

In addition, the bill would direct the 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 a contractor-wide error rate. The bill would also expand the requirement for contractors to monitor the accuracy of information given to pro-

viders, and would limit the liability of contractors for payment errors. CBO estimates that complying with these provisions would cost about \$27 million over the 2002–2006 period.

The bill also would instruct contractors to tailor their educational efforts toward providers with staffs of fewer than 26 people, or physicians with fewer than 11 staff members. The bill would authorize the appropriation of \$10 million in 2003 and in 2004 to provide additional educational services. CBO estimates that 80 percent of the authorized amount would be spent in the current fiscal year and 20 percent the year after.

Appeals and Claims Payment Reform.—H.R. 2768 would change the processes by which Medicare pays claims and adjudicates appeals by providers of payment denials. CBO estimates that implementing these provisions would cost \$9 million in 2002 and \$104 million over the 2002–2006 period.

Resubmission of claims.—Under current law, providers may pursue payment for claims initially submitted to contractors with errors and omissions either via resubmission of claims in some instances or via the appeals process. H.R. 2768 would direct CMS to expand the instances in which providers may resubmit claims directly to contractors. CBO expects that this provision would lead to an increase in the number of incomplete claims submitted and a 1 percent increase in the number of claims processed. We estimate that processing those incomplete claims would increase costs by \$5 million in 2002 and by \$46 million over the 2002–2006 period.

Reliance on guidance.—H.R. 2768 would prohibit any sanction (including recoupment of overpayments) of a provider who relies on written guidance from contractors. CBO assumes this provision would increase the number of requests for written guidance by 50 percent. Under current law, contractors are required to respond to those requests. CBO estimates that the cost to contractors of issuing written responses to the additional requests, and the cost to CMS of oversight of those responses, would total less than \$500,000 in 2002 and \$29 million over the 2002–2006 period.

Standardization of compliance actions.—The bill would also standardize existing policies regarding:

- Using random and non-random prepayment review;
- Using extrapolation after finding of overpayment;
- Enrolling providers and adjudicating appeals of enrollment denials;
- Communicating findings of overpayment to providers;
- Notifying providers regarding billing codes that the contractor suspects are being overused;
- Requiring providers to act within 45 days during the consent settlement process;
- Collecting overpayments from providers.

CBO estimates that implementing those provisions would cost \$28 million over the 2002–2006 period.

Appeals reform.—H.R. 2768 would modify the current appeals system. The bill would allow appellants to petition review boards for expedited access to judicial review outside of the Medicare review system. The bill would also require appellants to present all relevant evidence at the reconsideration level. These provisions are estimated to reduce administrative outlays by about \$6 million over

the 2002–2006 period because they are expected to reduce the caseload at the third and fourth level of appeals.

The bill would transfer certain administrative law judges (ALJs) from the Social Security Administration to the Department of Health and Human Services. CBO estimates that the costs of planning and implementing the transfer, and providing the ALJs with additional training on Medicare issues, would total \$8 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.

Demonstrations and New Program Areas.—H.R. 2768 would direct CMS to expand its programs to educate beneficiaries and providers. CBO estimates that implementing these provisions would cost \$9 million in 2002 and \$69 million during the 2002–2006 period.

The bill would create a demonstration project for the provision of technical services to small providers. Participating providers would receive education specifically related to their practice, as well as information about general Medicare billing and documentation requirements. Participants would contribute 25 percent of the costs of the technical assistance. The bill would authorize the appropriation of \$1 million in 2003 and \$6 million in 2004 for the demonstration.

The bill would also 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 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. 2768 would require CMS to develop two new ombudsman offices, for providers and beneficiaries, within the Medicare program. Each office would act as a liaison between either providers or beneficiaries and the agency. The offices would be responsible for offering advice and assistance to individuals regarding the program, as well as conveying the concerns of providers and beneficiaries to program officials. The bill would authorize such sums as may be necessary in 2002 and thereafter for these ombudsman offices. CBO estimates that the number of staff required to perform these functions would grow from 85 FTEs in 2002 to 155 FTEs in 2006. We estimate these ombudsman activities would cost \$54 million over the 2002–2006 period.

H.R. 2768 would also require CMS to establish a Council for Technology and Innovation within CMS. The Secretary would appoint an Executive Coordinator for the council. CBO estimates that CMS would spend about \$1 million a year to staff and operate the Council for Technology and Innovation.

Development of Policies, Procedures, and Time Lines.—H.R. 2768 would require CMS to develop new policies, procedures, and time lines with regard to the issuance of regulations, documentation

guidelines for evaluation and management services, and the Medicare Secondary Payer program. CBO estimates the cost of implementing these provisions would be \$9 million in 2002 and \$36 million during the 2002–2006 period.

Final regulations.—The bill would require CMS to create a time line for the publication of final regulations and 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.

CBO estimates that it would cost about \$9 million in 2002 to finalize existing interim final rules. We estimate the CMS would need to hire an additional 3 to 5 staff, at the GS–11 level or higher, and spend an additional \$10 million through 2006 to comply with the requirement to finalize all future interim regulations and to produce the required reports.

Documentation guidelines for evaluation and management (E&M) services.—H.R. 2768 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 development and implementing new E&M guidelines. Establishing new guidelines for E&M documentation would require the hiring of at least two FTEs for 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.

Medicare Secondary Payer program.—The Medicare Secondary Payer program requires providers and suppliers to collect insurance information from beneficiaries to determine whether Medicare will be the secondary payer on a claim. The bill would restrict Medicare from implementing special requirements for hospital-based laboratories that act as referral laboratories, with respect to gathering insurance information from patients, unless independent laboratories are also required to collect such information. Under current policy, referral laboratories, which conduct tests without direct contact with patients, would have to begin gathering this information beginning in January 2002. CBO estimates that the costs of complying with this provision would be negligible.

Medicare Coverage Policies.—H.R. 2768 would change the timing of CMS’s national coverage decisions concerning certain new technologies. Upon request by an applicant, the Secretary would be required, to the extent feasible, to coordinate reviews of coverage de-

cisions with the review for premarket approval conducted by the Food and Drug Administration. H.R. 2768 would require the Secretary to submit to the Congress a plan for achieving such coordination within six months. CBO estimates that establishing and operating the coordination process would cost \$1 million in 2002 and \$3 million over the 2002–2006 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. CBO estimates that the bill would not affect receipts and would have no significant effect on direct spending.

Estimated impact on state, local, and tribal governments: H.R. 2768 contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act. The requirement for public hospitals participating in the Medicare program to comply with OSHA's bloodborne pathogens standard would have cost implications for state and local governments. The current OSHA standard applies to all private-sector employers with one or more employees, as well as to federal civilian employees. This bill would extend the requirement to all hospitals participating in the Medicare program, including state and local public hospitals. About half of the states currently have bloodborne pathogen standards that apply to these hospitals that are at least as stringent as the federal standard. Public hospitals in the remaining states could face additional costs as a result of the new requirement. Those costs, however, would result from participating in Medicare, a voluntary federal program, and thus would not be costs of an intergovernmental mandate as defined in UMRA.

Estimated impact on the private sector: H.R. 2768 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.

V. OTHER MATTERS REQUIRED TO BE DISCUSSED UNDER THE RULES OF THE HOUSE

A. COMMITTEE OVERSIGHT FINDINGS AND RECOMMENDATIONS

In compliance with clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee reports that the need for this legislation was confirmed by the oversight hearings of the Subcommittee of Health. The hearings were as follows:

The Subcommittee on Health held a hearing on March 15, 2001 to examine how government can do its job better to ensure that beneficiaries are protected and that taxpayer dollars are used wisely and responsibly without placing undue burdens on providers. Testimony at the hearing was presented by the Office of the Inspector General, patient and provider groups and experts on the Medicare program.

On September 25, 2001, the Subcommittee held a hearing on H.R. 2768, which includes provisions for facilitating access by beneficiaries and providers to information on the Medicare program, for improving the administration of the Medicare program and for re-

ducing regulatory burden. The hearing included testimony from the Administration, the General Accounting Office, and health care providers.

B. SUMMARY OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

In compliance with clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, the Committee states that the primary purpose of H.R. 2768 is to create a more collaborative, less confrontational relationship between providers and CMS.

C. CONSTITUTIONAL AUTHORITY STATEMENT

In compliance with clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, relating to constitutional Authority, the Committee states that the Committee's action in reporting the bill is derived from Article I of the Constitution, Section 8 ("The Congress shall have power to lay and collect taxes, duties, imposts and excises, to pay the debts and to provide for * * * the general Welfare of the United States * * *").

VI. 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

* * * * *

TITLE XVIII—HEALTH INSURANCE FOR THE AGED AND DISABLED

* * * * *

NOTICE OF MEDICARE BENEFITS; MEDICARE AND MEDIGAP INFORMATION

SEC. 1804. (a) * * *

(b) The Secretary shall provide information via a toll-free telephone number on the programs under this title. *The Secretary shall provide, through the toll-free number 1-800-MEDICARE, for a means by which individuals seeking information about, or assistance with, such programs who phone such toll-free number are transferred (without charge) to appropriate entities for the provision of such information or assistance. Such toll-free number shall be the toll-free number listed for general information and assistance in the annual notice under subsection (a) instead of the listing of numbers of individual contractors.*

* * * * *

MEDICARE BENEFICIARY OMBUDSMAN

SEC. 1807. (a) *IN GENERAL.—The Secretary shall appoint within the Department of Health and Human Services a Medicare Bene-*

fiary Ombudsman who shall have expertise and experience in the fields of health care and advocacy.

(b) DUTIES.—The Medicare Beneficiary Ombudsman shall—

(1) receive complaints, grievances, and requests for information submitted by a medicare beneficiary, with respect to any aspect of the medicare program;

(2) provide assistance with respect to complaints, grievances, and requests referred to in paragraph (1), including—

(A) assistance in collecting relevant information for such beneficiaries, to seek an appeal of a decision or determination made by a fiscal intermediary, carrier, Medicare+Choice organization, or the Secretary; and

(B) assistance to such beneficiaries with any problems arising from disenrollment from a Medicare+Choice plan under part C; and

(3) submit annual reports to Congress and the Secretary that describe the activities of the Office and that include such recommendations for improvement in the administration of this title as the Ombudsman determines appropriate.

* * * * *

PART A—HOSPITAL INSURANCE BENEFITS FOR THE AGED AND DISABLED

* * * * *

CONDITIONS OF AND LIMITATIONS ON PAYMENT FOR SERVICES

Requirement of Requests and Certifications

SEC. 1814. (a) * * *

* * * * *

Payment for Hospice Care

(i)(1) * * *

* * * * *

(4) In the case of hospice care provided by a hospice program under arrangements under section 1861(dd)(5)(D) made by another hospice program, the hospice program that made the arrangements shall bill and be paid for the hospice care.

* * * * *

【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 adminis-

tration, 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 agree-

ment 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 agree-

ment, 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.]

* * * * *

PART B—SUPPLEMENTARY MEDICAL INSURANCE BENEFITS FOR THE AGED AND DISABLED

* * * * *

PAYMENT OF BENEFITS

SEC. 1833. (a) * * *

(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) on the basis of an itemized bill; or

(ii) on the basis of an assignment under the terms of which (I) the reasonable charge is the full charge for the service, (II) the physician or other person furnishing such service agrees not to charge (and to refund amounts already collected) for services for which payment under this title is denied under section 1154(a)(2) by reason of a determination under section 1154(a)(1)(B), and (III) the physician or other person furnishing such service agrees not to charge (and to refund amounts already collected) for such service if payment may not be made therefor by reason of the provisions of paragraph (1) of section 1862(a), and if the individual to whom such service was furnished was without fault in incurring the expenses of such service, and if the Secretary's determination that payment (pursuant to such assignment) was incorrect and was made subsequent to the third year following the year in which notice of such payment was sent to such individual; except that the Secretary may reduce such three-year period to not less than one year if he finds such reduction is consistent with the objectives of this title (except in the case of physicians' services and ambulance service furnished as described in section 1862(a)(4), other than for purposes of section 1870(f));

but (in the case of bills submitted, or requests for payment made, after March 1968) only if the bill is submitted, or a written request for payment is made in such other form as may be permitted under regulations, no later than the close of the calendar year following the year in which such service is furnished (deeming any service furnished in the last 3 months of any calendar year to have been furnished in the succeeding calendar year);

~~(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 reason-

able 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 payment 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 sub-

mitted 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 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 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) [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). [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 Secretary 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 D—MISCELLANEOUS PROVISIONS
 DEFINITIONS OF SERVICES, INSTITUTIONS, ETC.

SEC. 1861. For purposes of this title—

Spell of Illness

(a) * * *

* * * * *

Supplier

(d) The term “supplier” means, unless the context otherwise requires, a physician or other practitioner, a facility, or other entity (other than a provider of services) that furnishes items or services under this title.

* * * * *

Hospice Care; Hospice Program

(dd)(1) * * *

* * * * *

(5)(A) * * *

* * * * *

(D) In extraordinary, exigent, or other non-routine circumstances, such as unanticipated periods of high patient loads, staffing shortages due to illness or other events, or temporary travel of a patient outside a hospice program’s service area, a hospice program may enter into arrangements with another hospice program for the provision by that other program of services described in paragraph (2)(A)(ii)(I). The provisions of paragraph (2)(A)(ii)(II) shall apply with respect to the services provided under such arrangements.

* * * * *

EXCLUSIONS FROM COVERAGE AND MEDICARE AS SECONDARY PAYER

SEC. 1862. (a) * * *

* * * * *

(d) In the case of hospital services and physicians’ services that—

(1) are furnished, to an individual who is not enrolled in a Medicare+Choice plan under part C, by a hospital or a critical access hospital; and

(2) are needed to evaluate or stabilize an emergency medical condition (as defined in section 1852(d)(3)(B), relating to application of a prudent layperson rule) and that are provided to meet the requirements of section 1867,

such services shall be deemed to be reasonable and necessary for the diagnosis or treatment of illness or injury for purposes of subsection (a)(1)(A).

* * * * *

AGREEMENTS WITH PROVIDERS OF SERVICES; ENROLLMENT PROCESSES

SEC. 1866. (a)(1) Any provider of services (except a fund designated for purposes of section 1814(g) and section 1835(e)) shall be qualified to participate under this title and shall be eligible for payments under this title if it files with the Secretary an agreement—

(A) * * *

* * * * *

(R) to contract only with a health care clearinghouse (as defined in section 1171) that meets each standard and implementation specification adopted or established under part C of title XI on or after the date on which the health care clearinghouse is required to comply with the standard or specification, [and]

(S) in the case of a hospital that has a financial interest (as specified by the Secretary in regulations) in an entity to which individuals are referred as described in section 1861(ee)(2)(H)(ii), or in which such an entity has such a financial interest, or in which another entity has such a financial interest (directly or indirectly) with such hospital and such an entity, to maintain and disclose to the Secretary (in a form and manner specified by the Secretary) information on—

(i) * * *

* * * * *

(iii) the percentage of such individuals who received such services from such provider (or another such provider) [.] and

(T) in the case of hospitals that are not otherwise subject to the Occupational Safety and Health Act of 1970, to comply with the Bloodborne Pathogens standard under section 1910.1030 of title 29 of the Code of Federal Regulations (or as subsequently redesignated).

* * * * *

(b)(1) * * *

* * * * *

(4)(A) A hospital that fails to comply with the requirement of subsection (a)(1)(T) (relating to the Bloodborne Pathogens standard) is subject to a civil money penalty in an amount described in subparagraph (B), but is not subject to termination of an agreement under this section.

(B) The amount referred to in subparagraph (A) is an amount that is similar to the amount of civil penalties that may be imposed under section 17 of the Occupational Safety and Health Act of 1970 for a violation of the Bloodborne Pathogens standard referred to in subsection (a)(1)(T) by a hospital that is subject to the provisions of such Act.

(C) A civil money penalty under this paragraph shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A are imposed and collected under that section.

* * * * *

(h)(1) * * *

* * * * *

(3) *The provisions of section 1869(b)(2) shall apply with respect to determinations described in paragraph (1) in the same manner as they apply to a provider of services that has filed an appeal under section 1869(b)(1).*

* * * * *

(j) *ENROLLMENT PROCESS FOR PROVIDERS OF SERVICES AND SUPPLIERS.—*

(1) *IN GENERAL.—The Secretary shall establish by regulation a process for the enrollment of providers of services and suppliers under this title.*

(2) *APPEAL PROCESS.—Such process shall provide—*

(A) *a method by which providers of services and suppliers whose application to enroll (or, if applicable, to renew enrollment) are denied are provided a mechanism to appeal such denial; and*

(B) *prompt deadlines for actions on applications for enrollment (and, if applicable, renewal of enrollment) and for consideration of appeals.*

* * * * *

PRACTICING PHYSICIANS ADVISORY COUNCIL; MEDICARE PROVIDER OMBUDSMAN

SEC. 1868. (a) *PRACTICING PHYSICIANS ADVISORY COUNCIL.—(1) The Secretary shall appoint, based upon nominations submitted by medical organizations representing physicians, a Practicing Physicians Advisory Council (in this section in this subsection referred to as the “Council”) to be composed of 15 physicians, each of whom has submitted at least 250 claims for physicians’ services under this title in the previous year. At least 11 of the members of the Council shall be physicians described in section 1861(r)(1) and the members of the Council shall include both participating and non-participating physicians and physicians practicing in rural areas and underserved urban areas.*

[(b)] (2) *The Council shall meet once during each calendar quarter to discuss certain proposed changes in regulations and carrier manual instructions related to physician services identified by the Secretary. To the extent feasible and consistent with statutory deadlines, such consultation shall occur before the publication of such proposed changes.*

[(c)] (3) *Members of the Council shall be entitled to receive reimbursement of expenses and per diem in lieu of subsistence in the same manner as other members of advisory councils appointed by the Secretary are provided such reimbursement and per diem under this title.*

(b) *MEDICARE PROVIDER OMBUDSMAN.—The Secretary shall appoint a Medicare Provider Ombudsman. The Ombudsman shall—*

(1) *provide assistance, on a confidential basis, to providers of services and suppliers with respect to complaints, grievances, and requests for information concerning the programs under this title (including provisions of title XI insofar as they relate to this title and are not administered by the Office of the Inspec-*

tor General of the Department of Health and Human Services) and in the resolution of unclear or conflicting guidance given by the Secretary and medicare contractors to such providers of services and suppliers regarding such programs and provisions and requirements under this title and such provisions; and

(2) submit recommendations to the Secretary for improvement in the administration of this title and such provisions, including—

(A) recommendations to respond to recurring patterns of confusion in this title and such provisions (including recommendations regarding suspending imposition of sanctions where there is widespread confusion in program administration), and

(B) recommendations to provide for an appropriate and consistent response (including not providing for audits) in cases of self-identified overpayments by providers of services and suppliers.

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) * * *

(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.

* * * * *

(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) (other than an appeal filed under paragraph (1)(F)) 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 it 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 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 no review panel has 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 no review panel has the 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 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 AMOUNTS IN CONTROVERSY.*—Where a provider of services or supplier seeks judicial review pursuant to this paragraph, the amount in controversy 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 Hospital 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 or suppliers under this Act.

(D) REVIEW PANELS.—For purposes of this subsection, a “review panel” is an administrative law judge, the Departmental Appeals Board, a qualified independent contractor (as defined in subsection (c)(2)), or an entity designated by the Secretary for purposes of making determinations under this paragraph.

(3) REQUIRING FULL AND EARLY PRESENTATION OF EVIDENCE BY PROVIDERS.—A provider of services or supplier may not introduce evidence in any appeal under this section that was not presented at the reconsideration conducted by the qualified independent contractor under subsection (c), unless there is good cause which precluded the introduction of such evidence at or before that reconsideration.

* * * * *

(g) MEDICARE ADMINISTRATIVE LAW JUDGES.—

(1) TRANSITION PLAN.—Not later than October 1, 2003, the Commissioner of Social Security and the Secretary shall develop and implement a plan under which the functions of administrative law judges responsible for hearing cases under this title (and related provisions in title XI) shall be transferred from the responsibility of the Commissioner and the Social Security Administration to the Secretary and the Department of Health and Human Services. The plan shall include recommendations with respect to—

(A) the number of administrative law judges and support staff required to hear and decide such cases in a timely manner; and

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

Nothing in this subsection shall be construed as affecting the independence of administrative law judges from the Department of Health and Human Services and from medicare contractors in carrying out their responsibilities for hearing and deciding cases.

(2) INCREASED FINANCIAL SUPPORT.—In addition to any amounts otherwise appropriated, 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 to increase the number of administrative law judges described in paragraph (1) and to improve education and training for such judges and their staffs in carrying out functions under this title, \$5,000,000 for fiscal year 2003 and such sums as are necessary for fiscal year 2004 and each subsequent fiscal year.

(3) SUBMITTAL OF PLAN TO CONGRESS AND GAO; REPORT OF GAO.—Not later than July 1, 2003, the Secretary shall submit to the Committee on Ways and Means of the House of Representatives, the Committee on Finance of the Senate, and the Comptroller General of the United States the terms of the plan developed under paragraph (1). No later than September 1, 2003, the Comptroller General shall submit to such Committees a report containing an evaluation of the terms of such plan.

* * * * *

REGULATIONS

SEC. 1871. (a)(1) * * *

* * * * *

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

(B) *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. If the Secretary intends to vary such timeline with respect to the publication of a final regulation, the Secretary shall cause to have published in the Federal Register notice of the different timeline by not later than the end of the comment period respecting such regulation. Such notice shall include a brief explanation of the justification for such variation.*

(C) *In the case of interim final regulations, upon the expiration of the regular timeline established under this paragraph for the publication of a final regulation after opportunity for public comment, the interim final regulation shall not continue in effect unless the Secretary publishes a notice of continuation of the regulation that includes an explanation of why the regular timeline was not complied with. If such a notice is published, the regular timeline for publication of the final regulation shall be treated as having begun again as of the date of publication of the notice.*

(D) *The Secretary shall annually submit to Congress a report that describes the instances in which the Secretary failed to publish a final regulation within the applicable timeline under this paragraph and that provides an explanation for such failures.*

(4) *If the Secretary publishes notice of proposed rulemaking relating to a regulation (including an interim final regulation), insofar as such final regulation includes a provision that is not a logical outgrowth of such notice of proposed rulemaking, 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) *The Secretary shall issue proposed or final (including interim final) regulations to carry out this title only on one business day of every month unless publication on another date is necessary to comply with requirements under law.*

(2) *The Secretary shall coordinate issuance of new regulations relating to a category of provider of services or suppliers based on an analysis of the collective impact of regulatory changes on that category of providers or suppliers.*

(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 date the change was issued, unless the Secretary determines that such retroactive application would have a positive impact on*

beneficiaries or providers of services and suppliers or would be necessary to comply with statutory requirements.

(B) A substantive change in regulations, manual instructions, interpretative rules, statements of policy, or guidelines of general applicability under this title shall not become effective until at least 30 days after the Secretary issues the substantive change.

(C) No action shall be taken against a provider of services or supplier with respect to noncompliance with such a substantive change for items and services furnished before the effective date of such a change.

(2)(A) If—

(i) a provider of services or supplier follows the written guidance (which may be transmitted electronically) provided by the Secretary or by a medicare contractor (as defined in section 1889(f)) acting within the scope of the contractor's contract authority, with respect to the furnishing of items or services and submission of a claim for benefits for such items or services with respect to such provider or supplier;

(ii) the Secretary determines that the provider of services or supplier has accurately presented the circumstances relating to such items, services, and claim to the contractor in writing; and

(iii) the guidance was in error;

the provider of services or supplier shall not be subject to any sanction (including any penalty or requirement for repayment of any amount) if the provider of services or supplier reasonably relied on such guidance.

(B) Subparagraph (A) shall not be construed as preventing the recoupment or repayment (without any additional penalty) relating to an overpayment insofar as the overpayment was solely the result of a clerical or technical operational error.

* * * * *

CONTRACTS WITH MEDICARE ADMINISTRATIVE CONTRACTORS

SEC. 1874A. (a) AUTHORITY.—

(1) **AUTHORITY TO ENTER INTO CONTRACTS.**—The Secretary may enter into contracts with any entity to serve as a medicare administrative contractor with respect to the performance of any or all of the functions described in paragraph (3) or parts of those functions (or, to the extent provided in a contract, to secure performance thereof by other entities).

(2) **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 or supplier (or class of such providers of services 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 re-

lation to that individual, provider of services or supplier or class of provider of services or supplier.

(3) *FUNCTIONS DESCRIBED.*—The functions referred to in paragraph (1) 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, 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.*—Providing education and outreach to individuals entitled to benefits under part A or enrolled under part B, or both, and providing assistance to those individuals with specific issues, concerns or problems.

(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 or suppliers.

(E) *COMMUNICATION WITH PROVIDERS.*—Communicating to providers of services and suppliers any information or instructions furnished to the medicare administrative contractor by the Secretary and serving as a channel of communication from providers of services and suppliers to the Secretary.

(F) *PROVIDER EDUCATION AND TECHNICAL ASSISTANCE.*—Performing the functions relating to provider education, training, and technical assistance.

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

(4) *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 activities 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.

(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, taking into account performance quality as well as price and other factors.

(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.—Functions may be transferred among medicare administrative contractors consistent with the provisions of this paragraph. The Secretary shall ensure that performance quality is considered in such transfers.

(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, quality of services provided, and other matters as the Secretary finds pertinent.

(3) DEVELOPMENT OF SPECIFIC PERFORMANCE REQUIREMENTS.—In developing contract performance requirements, the Secretary shall develop performance requirements to carry out the specific requirements applicable under this title to a function described in subsection (a)(3). In developing such requirements, the Secretary may consult with providers of services and suppliers and organizations and agencies performing functions necessary to carry out the purposes of this section with respect to such performance requirements.

(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)(3)(B).

(2) **PROHIBITION ON MANDATES FOR CERTAIN DATA COLLECTION.**—The Secretary may not require, as a condition of entering into 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.**—A medicare administrative contractor shall be liable to the United States for a payment referred to in paragraph (1) or (2) if, in connection with such payment, an individual referred to in either such paragraph acted with gross negligence or intent to defraud the United States.

(4) **INDEMNIFICATION BY SECRETARY.**—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, if due care was exercised by the contractor or person in the performance of such duty, function, or activity.

(e) **INCENTIVES TO IMPROVE CONTRACTOR PERFORMANCE IN PROVIDER EDUCATION AND OUTREACH.**—

(1) **METHODOLOGY TO MEASURE CONTRACTOR ERROR RATES.**—In order to give medicare administrative contractors an incentive to implement effective education and outreach programs for providers of services and suppliers, the Secretary shall, in consultation with representatives of providers and suppliers, de-

velop and implement by October 1, 2003, a methodology to measure the specific claims payment error rates of such contractors in the processing or reviewing of medicare claims.

(2) *IDENTIFICATION OF BEST PRACTICES.*—The Secretary shall identify the best practices developed by individual medicare administrative contractors for educating providers of services and suppliers and how to encourage the use of such best practices nationwide.

(f) *RESPONSE TO INQUIRIES; TOLL-FREE LINES.*—

(1) *CONTRACTOR RESPONSIBILITY.*—Each medicare administrative contractor shall, for those providers of services and suppliers which submit claims to the contractor for claims processing—

(A) respond in a clear, concise, and accurate manner to specific billing and cost reporting questions of providers of services and suppliers;

(B) maintain a toll-free telephone number at which providers of services and suppliers may obtain information regarding billing, coding, and other appropriate information under this title;

(C) maintain a system for identifying (and disclosing, upon request) who provides the information referred to in subparagraphs (A) and (B); and

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

(2) *EVALUATION.*—In conducting evaluations of individual medicare administrative contractors, the Secretary shall take into account the results of the monitoring conducted under paragraph (1)(D). The Secretary shall, in consultation with organizations representing providers of services and suppliers, establish standards relating to the accuracy, consistency, and timeliness of the information so provided.

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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 (i), including under section 1893) in order to maximize the effectiveness of Federal education efforts for providers of services and suppliers.

(b) *ENHANCED EDUCATION AND TRAINING.*—

(1) *ADDITIONAL RESOURCES.*—For each of fiscal years 2003 and 2004, there are authorized to be appropriated to the Secretary (in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) \$10,000,000 .

(2) *USE.*—The funds made available under paragraph (1) shall be used to increase the conduct by medicare contractors of education and training of providers of services and suppliers regarding billing, coding, and other appropriate items.

(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 tailor such activities

to meet the special needs of small providers of services or suppliers (as defined in paragraph (2)).

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

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

(B) a supplier with fewer than 10 full-time-equivalent employees.

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

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

(2) includes other published materials of the contractor, that relate to providers of services and suppliers under the programs under this title (and title XI insofar as it relates to such programs).

(e) **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 or suppliers for the purpose of conducting any type of audit or prepayment review.

(f) **CONSTRUCTION.**—Nothing in this section or section 1893(g) shall be construed as providing for disclosure by a medicare contractor—

(1) of the screens used for identifying claims that will be subject to medical review; or

(2) of information that would compromise pending law enforcement activities or reveal findings of law enforcement-related audits.

(g) **DEFINITIONS.**—For purposes of this section, the term “medicare contractor” includes the following:

(1) A medicare administrative contractor with a contract under section 1874A, including 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 or supplier an entity that has no authority under this title or title IX with respect to such activities and such provider of services or supplier.

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MEDICARE INTEGRITY PROGRAM

SEC. 1893. (a) * * *

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(f) **RECOVERY OF OVERPAYMENTS AND PREPAYMENT REVIEW.**—

(1) **USE OF REPAYMENT PLANS.**—

(A) **IN GENERAL.**—If the repayment, within 30 days by a provider of services or supplier, of an overpayment under

this title would constitute a hardship (as defined in subparagraph (B)), subject to subparagraph (C), the Secretary shall enter into a plan (which meets terms and conditions determined to be appropriate by the Secretary) with the provider of services or supplier for the offset or repayment of such overpayment over a period of not longer than 3 years, or in the case of extreme hardship (as determined by the Secretary) over a period of not longer than 5 years. Interest shall accrue on the balance through the period of repayment.

(B) HARDSHIP.—

(i) IN GENERAL.—For purposes of subparagraph (A), the repayment of an overpayment (or overpayments) within 30 days is deemed to constitute a hardship if—

(I) in the case of a provider of services that files cost reports, the aggregate amount of the overpayments exceeds 10 percent of the amount paid under this title to the provider of services for the cost reporting period covered by the most recently submitted cost report; or

(II) in the case of another provider of services or supplier, the aggregate amount of the overpayments exceeds 10 percent of the amount paid under this title to the provider of services or supplier for the previous calendar year.

(ii) RULE OF APPLICATION.—The Secretary shall establish rules for the application of this subparagraph in the case of a provider of services or supplier that was not paid under this title during the previous year or was paid under this title only during a portion of that year.

(iii) TREATMENT OF PREVIOUS OVERPAYMENTS.—If a provider of services or supplier has entered into a repayment plan under subparagraph (A) with respect to a specific overpayment amount, such payment amount under the repayment plan shall not be taken into account under clause (i) with respect to subsequent overpayment amounts.

(C) EXCEPTIONS.—Subparagraph (A) shall not apply if the Secretary has reason to suspect that the provider of services or supplier may file for bankruptcy or otherwise cease to do business or if 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 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.

(2) LIMITATION ON RECOUPMENT UNTIL DETERMINATION BY QUALIFIED INDEPENDENT CONTRACTOR.—

(A) IN GENERAL.—In the case of a provider of services 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 paragraph (9)) to recoup the overpayment until the date the decision on the reconsideration has been rendered.

(B) COLLECTION WITH INTEREST.—Insofar as the determination on such appeal is against the provider of services or supplier, interest on the overpayment shall accrue on and after the date of the original notice of overpayment. Insofar as such determination against the provider of services or supplier is later reversed, the Secretary shall provide for repayment of the amount recouped plus interest at the same rate as would apply under the previous sentence for the period in which the amount was recouped.

(3) STANDARDIZATION OF RANDOM PREPAYMENT REVIEW.—

(A) IN GENERAL.—A medicare contractor may conduct random prepayment review only to develop a contractor-wide or program-wide claims payment error rates or under such additional circumstances as may be provided under regulations, developed in consultation with providers of services and suppliers.

(B) CONSTRUCTION.—Nothing in subparagraph (A) shall be construed as preventing the denial of payments for claims actually reviewed under a random prepayment review.

(4) 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).

(5) PROVISION OF SUPPORTING DOCUMENTATION.—*In the case of a provider of services or supplier with respect to which amounts were previously overpaid, a medicare contractor may 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.*

(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 or supplier a consent settlement, the Secretary shall—*

(i) communicate to the provider of services or supplier in a non-threatening manner that, based on a review of the medical records requested by the Secretary, a preliminary analysis indicates that there would be an overpayment; and

(ii) provide for a 45-day period during which the provider of services or supplier may furnish additional in-

formation 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 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 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 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 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 or supplier agrees not to appeal the claims involved.

(7) **LIMITATIONS ON NON-RANDOM PREPAYMENT REVIEW.**—

(A) **LIMITATION ON INITIATION OF NON-RANDOM PREPAYMENT REVIEW.**—A medicare contractor may not initiate non-random prepayment review of a provider of services or supplier based on the initial identification by that provider of services or supplier of an improper billing practice unless there is a sustained or high level of payment error (as defined in paragraph (4)(A)).

(B) **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.

(8) **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 or supplier under this title, the contractor shall provide the provider of services or supplier with written notice 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 or supplier under this title, the contractor shall provide for an exit conference with the provider or supplier during which the contractor shall—

(i) give the provider of services or supplier a full review and explanation of the findings of the audit in a manner that is understandable to the provider of serv-

ices or supplier and permits the development of an appropriate corrective action plan;

(ii) inform the provider of services or supplier of the appeal rights under this title;

(iii) give the provider of services 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 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 or reveal findings of law enforcement-related audits.

(9) DEFINITIONS.—For purposes of this subsection:

(A) MEDICARE CONTRACTOR.—The term “medicare contractor” has the meaning given such term in section 1889(f).

(B) RANDOM PREPAYMENT REVIEW.—The term “random prepayment review” means a demand for the production of records or documentation absent cause with respect to a claim.

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

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