

AMENDMENT-IN-THE-NATURE-OF-A-SUBSTITUTE
OFFERED BY MR. THOMAS
TO H.R. 2768, AS REPORTED BY THE
SUBCOMMITTEE ON HEALTH

Strike all after the enacting clause and insert the following:

1 **SECTION 1. SHORT TITLE; AMENDMENTS TO SOCIAL SE-**
2 **CURITY ACT; TABLE OF CONTENTS.**

3 (a) SHORT TITLE.—This Act may be cited as the “Medi-
4 care Regulatory and Contracting Reform Act of 2001”.

5 (b) AMENDMENTS TO SOCIAL SECURITY ACT.—Except as
6 otherwise specifically provided, whenever in this Act an amend-
7 ment is expressed in terms of an amendment to or repeal of
8 a section or other provision, the reference shall be considered
9 to be made to that section or other provision of the Social Se-
10 curity Act.

11 (c) TABLE OF CONTENTS.—The table of contents of this
12 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.

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

15 (1) to compromise or affect existing legal authority for
16 addressing fraud or abuse, whether it be criminal prosecu-

1 tion, civil enforcement, or administrative remedies, includ-
2 ing under sections 3729 through 3733 of title 31, United
3 States Code (known as the False Claims Act); or

4 (2) to prevent or impede the Department of Health
5 and Human Services in any way from its ongoing efforts
6 to eliminate waste, fraud, and abuse in the medicare pro-
7 gram.

8 Furthermore, the consolidation of medicare administrative con-
9 tracting set forth in this Act does not constitute consolidation
10 of the Federal Hospital Insurance Trust Fund and the Federal
11 Supplementary Medical Insurance Trust Fund or reflect any
12 position on that issue.

13 (e) USE OF TERM SUPPLIER IN MEDICARE.—Section
14 1861 (42 U.S.C. 1395x) is amended by inserting after sub-
15 section (c) the following new subsection:

16 “Supplier

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

21 **SEC. 2. ISSUANCE OF REGULATIONS.**

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

24 (1) IN GENERAL.—Section 1871 (42 U.S.C. 1395hh)
25 is amended by adding at the end the following new sub-
26 section:

27 “(d)(1) The Secretary shall issue proposed or final (includ-
28 ing interim final) regulations to carry out this title only on one
29 business day of every month unless publication on another date
30 is necessary to comply with requirements under law.

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

35 (2) REPORT ON PUBLICATION OF REGULATIONS ON A
36 QUARTERLY BASIS.—Not later than 3 years after the date
37 of the enactment of this Act, the Secretary of Health and

1 Human Services shall submit to Congress a report on the
2 feasibility of requiring that regulations described in section
3 1871(d) of the Social Security Act only be promulgated on
4 a single day every calendar quarter.

5 (3) EFFECTIVE DATE.—The amendment made by
6 paragraph (1) shall apply to regulations promulgated on or
7 after the date that is 30 days after the date of the enact-
8 ment of this Act.

9 (b) REGULAR TIMELINE FOR PUBLICATION OF FINAL
10 RULES.—

11 (1) IN GENERAL.—Section 1871(a) (42 U.S.C.
12 1395hh(a)) is amended by adding at the end the following
13 new paragraph:

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

19 “(B) Such timeline may vary among different regulations
20 based on differences in the complexity of the regulation, the
21 number and scope of comments received, and other relevant
22 factors. If the Secretary intends to vary such timeline with re-
23 spect to the publication of a final regulation, the Secretary
24 shall cause to have published in the Federal Register notice of
25 the different timeline by not later than the end of the comment
26 period respecting such regulation. Such notice shall include a
27 brief explanation of the justification for such variation.

28 “(C) In the case of interim final regulations, upon the ex-
29 piration of the regular timeline established under this para-
30 graph for the publication of a final regulation after opportunity
31 for public comment, the interim final regulation shall not con-
32 tinue in effect unless the Secretary publishes a notice of con-
33 tinuation of the regulation that includes an explanation of why
34 the regular timeline was not complied with. If such a notice is
35 published, the regular timeline for publication of the final regu-
36 lation shall be treated as having begun again as of the date of
37 publication of the notice.

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

6 (2) EFFECTIVE DATE.—The amendment made by
7 paragraph (1) shall take effect on the date of the enact-
8 ment of this Act. The Secretary of Health and Human
9 Services shall provide for an appropriate transition to take
10 into account the backlog of previously published interim
11 final regulations.

12 (c) LIMITATIONS ON NEW MATTER IN FINAL REGULA-
13 TIONS.—

14 (1) IN GENERAL.—Section 1871(a) (42 U.S.C.
15 1395hh(a)), as amended by subsection (b), is further
16 amended by adding at the end the following new para-
17 graph:

18 “(4) If the Secretary publishes notice of proposed rule-
19 making relating to a regulation (including an interim final reg-
20 ulation), insofar as such final regulation includes a provision
21 that is not a logical outgrowth of such notice of proposed rule-
22 making, that provision shall be treated as a proposed regulation
23 and shall not take effect until there is the further opportunity
24 for public comment and a publication of the provision again as
25 a final regulation.”.

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

29 **SEC. 3. COMPLIANCE WITH CHANGES IN REGULATIONS**
30 **AND POLICIES.**

31 (a) NO RETROACTIVE APPLICATION OF SUBSTANTIVE
32 CHANGES; TIMELINE FOR COMPLIANCE WITH SUBSTANTIVE
33 CHANGES AFTER NOTICE.—Section 1871 (42 U.S.C. 1395hh),
34 as amended by section 2(a), is amended by adding at the end
35 the following new subsection:

36 “(e)(1)(A) A substantive change in regulations, manual in-
37 structions, interpretative rules, statements of policy, or guide-

1 lines of general applicability under this title shall not be applied
2 (by extrapolation or otherwise) retroactively to items and serv-
3 ices furnished before the date the change was issued, unless the
4 Secretary determines that such retroactive application would
5 have a positive impact on beneficiaries or providers of services
6 and suppliers or would be necessary to comply with statutory
7 requirements.

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

13 “(C) No action shall be taken against a provider of serv-
14 ices or supplier with respect to noncompliance with such a sub-
15 stantive change for items and services furnished before the ef-
16 fective date of such a change.”.

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

20 “(2)(A) If—

21 “(i) a provider of services or supplier follows the writ-
22 ten guidance (which may be transmitted electronically) pro-
23 vided by the Secretary or by a medicare contractor (as de-
24 fined in section 1889(g)) acting within the scope of the
25 contractor’s contract authority, with respect to the fur-
26 nishing of items or services and submission of a claim for
27 benefits for such items or services with respect to such pro-
28 vider or supplier;

29 “(ii) the Secretary determines that the provider of
30 services or supplier has accurately presented the cir-
31 cumstances relating to such items, services, and claim to
32 the contractor in writing; and

33 “(iii) the guidance was in error;

34 the provider of services or supplier shall not be subject to any
35 sanction (including any penalty or requirement for repayment
36 of any amount) if the provider of services or supplier reason-
37 ably relied on such guidance.

1 “(B) Subparagraph (A) shall not be construed as pre-
2 venting the recoupment or repayment (without any additional
3 penalty) relating to an overpayment insofar as the overpayment
4 was solely the result of a clerical or technical operational
5 error.”.

6 (c) GAO STUDY ON ADVISORY OPINION AUTHORITY.—

7 (1) STUDY.—The Comptroller General of the United
8 States shall conduct a study to determine the feasibility
9 and appropriateness of establishing in the Secretary of
10 Health and Human Services and the Secretary’s contrac-
11 tors authority to provide legally binding advisory opinions
12 on appropriate interpretation and application of regulations
13 to carry out the medicare program under title XVIII of the
14 Social Security Act. Such study shall examine the appro-
15 priate timeframe for issuing such advisory opinions, as well
16 as the need for additional staff and funding to provide such
17 opinions.

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

21 **SEC. 4. INCREASED FLEXIBILITY IN MEDICARE ADMIN-**
22 **ISTRATION.**

23 (a) CONSOLIDATION AND FLEXIBILITY IN MEDICARE AD-
24 MINISTRATION.—

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

27 “CONTRACTS WITH MEDICARE ADMINISTRATIVE CONTRACTORS

28 “SEC. 1874A. (a) AUTHORITY.—

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

36 “(2) MEDICARE ADMINISTRATIVE CONTRACTOR DE-
37 FINED.—For purposes of this title and title XI—

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

4 “(B) APPROPRIATE MEDICARE ADMINISTRATIVE
5 CONTRACTOR.—With respect to the performance of a
6 particular function or activity in relation to an indi-
7 vidual entitled to benefits under part A or enrolled
8 under part B, or both, a specific provider of services or
9 supplier (or class of such providers of services or sup-
10 pliers), the ‘appropriate’ medicare administrative con-
11 tractor is the medicare administrative contractor that
12 has a contract under this section with respect to the
13 performance of that function or activity in relation to
14 that individual, provider of services or supplier or class
15 of provider of services or supplier.

16 “(3) FUNCTIONS DESCRIBED.—The functions referred
17 to in paragraph (1) are payment functions, provider serv-
18 ices functions, and beneficiary services functions as follows:

19 “(A) DETERMINATION OF PAYMENT AMOUNTS.—
20 Determining (subject to the provisions of section 1878
21 and to such review by the Secretary as may be provided
22 for by the contracts) the amount of the payments re-
23 quired pursuant to this title to be made to providers of
24 services, suppliers and individuals.

25 “(B) MAKING PAYMENTS.—Making payments de-
26 scribed in subparagraph (A) (including receipt, dis-
27 bursement, and accounting for funds in making such
28 payments).

29 “(C) BENEFICIARY EDUCATION AND ASSIST-
30 ANCE.—Providing education and outreach to individ-
31 uals entitled to benefits under part A or enrolled under
32 part B, or both, and providing assistance to those indi-
33 viduals with specific issues, concerns or problems.

34 “(D) PROVIDER CONSULTATIVE SERVICES.—Pro-
35 viding consultative services to institutions, agencies,
36 and other persons to enable them to establish and
37 maintain fiscal records necessary for purposes of this

1 title and otherwise to qualify as providers of services or
2 suppliers.

3 “(E) COMMUNICATION WITH PROVIDERS.—Com-
4 municating to providers of services and suppliers any
5 information or instructions furnished to the medicare
6 administrative contractor by the Secretary and serving
7 as a channel of communication from providers of serv-
8 ices and suppliers to the Secretary.

9 “(F) PROVIDER EDUCATION AND TECHNICAL AS-
10 SISTANCE.—Performing the functions relating to pro-
11 vider education, training, and technical assistance.

12 “(G) ADDITIONAL FUNCTIONS.—Performing such
13 other functions as are necessary to carry out the pur-
14 poses of this title.

15 “(4) RELATIONSHIP TO MIP CONTRACTS.—

16 “(A) NONDUPLICATION OF DUTIES.—In entering
17 into contracts under this section, the Secretary shall
18 assure that functions of medicare administrative con-
19 tractors in carrying out activities under parts A and B
20 do not duplicate activities carried out under the Medi-
21 care Integrity Program under section 1893. The pre-
22 vious sentence shall not apply with respect to the activ-
23 ity described in section 1893(b)(5) (relating to prior
24 authorization of certain items of durable medical equip-
25 ment under section 1834(a)(15)).

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

30 “(b) CONTRACTING REQUIREMENTS.—

31 “(1) USE OF COMPETITIVE PROCEDURES.—

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

1 under this section, taking into account performance
2 quality as well as price and other factors.

3 “(B) RENEWAL OF CONTRACTS.—The Secretary
4 may renew a contract with a medicare administrative
5 contractor under this section from term to term with-
6 out regard to section 5 of title 41, United States Code,
7 or any other provision of law requiring competition, if
8 the medicare administrative contractor has met or ex-
9 ceeded the performance requirements applicable with
10 respect to the contract and contractor, except that the
11 Secretary shall provide for the application of competi-
12 tive procedures under such a contract not less fre-
13 quently than once every five years.

14 “(C) TRANSFER OF FUNCTIONS.—Functions may
15 be transferred among medicare administrative contrac-
16 tors consistent with the provisions of this paragraph.
17 The Secretary shall ensure that performance quality is
18 considered in such transfers.

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

23 “(2) COMPLIANCE WITH REQUIREMENTS.—No con-
24 tract under this section shall be entered into with any
25 medicare administrative contractor unless the Secretary
26 finds that such medicare administrative contractor will per-
27 form its obligations under the contract efficiently and effec-
28 tively and will meet such requirements as to financial re-
29 sponsibility, legal authority, quality of services provided,
30 and other matters as the Secretary finds pertinent.

31 “(3) DEVELOPMENT OF SPECIFIC PERFORMANCE RE-
32 QUIREMENTS.—In developing contract performance require-
33 ments, the Secretary shall develop performance require-
34 ments to carry out the specific requirements applicable
35 under this title to a function described in subsection (a)(3).
36 In developing such requirements, the Secretary may consult
37 with providers of services and suppliers and organizations

1 and agencies performing functions necessary to carry out
2 the purposes of this section with respect to such perform-
3 ance requirements.

4 “(4) INFORMATION REQUIREMENTS.—The Secretary
5 shall not enter into a contract with a medicare administra-
6 tive contractor under this section unless the contractor
7 agrees—

8 “(A) to furnish to the Secretary such timely infor-
9 mation and reports as the Secretary may find nec-
10 essary in performing his functions under this title; and

11 “(B) to maintain such records and afford such ac-
12 cess thereto as the Secretary finds necessary to assure
13 the correctness and verification of the information and
14 reports under subparagraph (A) and otherwise to carry
15 out the purposes of this title.

16 “(5) SURETY BOND.—A contract with a medicare ad-
17 ministrative contractor under this section may require the
18 medicare administrative contractor, and any of its officers
19 or employees certifying payments or disbursing funds pur-
20 suant to the contract, or otherwise participating in carrying
21 out the contract, to give surety bond to the United States
22 in such amount as the Secretary may deem appropriate.

23 “(c) TERMS AND CONDITIONS.—

24 “(1) IN GENERAL.—A contract with any medicare ad-
25 ministrative contractor under this section may contain such
26 terms and conditions as the Secretary finds necessary or
27 appropriate and may provide for advances of funds to the
28 medicare administrative contractor for the making of pay-
29 ments by it under subsection (a)(3)(B).

30 “(2) PROHIBITION ON MANDATES FOR CERTAIN DATA
31 COLLECTION.—The Secretary may not require, as a condi-
32 tion of entering into a contract under this section, that the
33 medicare administrative contractor match data obtained
34 other than in its activities under this title with data used
35 in the administration of this title for purposes of identi-
36 fying situations in which the provisions of section 1862(b)
37 may apply.

1 “(d) LIMITATION ON LIABILITY OF MEDICARE ADMINIS-
2 TRATIVE CONTRACTORS AND CERTAIN OFFICERS.—

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

8 “(2) DISBURSING OFFICER.—No disbursing officer
9 shall, in the absence of gross negligence or intent to de-
10 fraud the United States, be liable with respect to any pay-
11 ment by such officer under this section if it was based upon
12 an authorization (which meets the applicable requirements
13 for such internal controls established by the Comptroller
14 General) of a certifying officer designated as provided in
15 paragraph (1) of this subsection.

16 “(3) LIABILITY OF MEDICARE ADMINISTRATIVE CON-
17 TRACTOR.—A medicare administrative contractor shall be
18 liable to the United States for a payment referred to in
19 paragraph (1) or (2) if, in connection with such payment,
20 an individual referred to in either such paragraph acted
21 with gross negligence or intent to defraud the United
22 States.

23 “(4) INDEMNIFICATION BY SECRETARY.—The Sec-
24 retary shall make payment to a medicare administrative
25 contractor under contract with the Secretary pursuant to
26 this section, or to any member or employee thereof, or to
27 any person who furnishes legal counsel or services to such
28 medicare administrative contractor, in an amount equal to
29 the reasonable amount of the expenses incurred, as deter-
30 mined by the Secretary, in connection with the defense of
31 any civil suit, action, or proceeding brought against such
32 medicare administrative contractor or person related to the
33 performance of any duty, function, or activity under such
34 contract, if due care was exercised by the contractor or per-
35 son in the performance of such duty, function, or activity.”.

36 “(2) CONSIDERATION OF INCORPORATION OF CURRENT
37 LAW STANDARDS.—In developing contract performance re-

1 quirements under section 1874A(b) of the Social Security
2 Act, as inserted by paragraph (1), the Secretary of Health
3 and Human Services shall consider inclusion of the per-
4 formance standards described in sections 1816(f)(2) of
5 such Act (relating to timely processing of reconsiderations
6 and applications for exemptions) and section 1842(b)(2)(B)
7 of such Act (relating to timely review of determinations and
8 fair hearing requests), as such sections were in effect be-
9 fore the date of the enactment of this Act.

10 (b) CONFORMING AMENDMENTS TO SECTION 1816 (RE-
11 LATING TO FISCAL INTERMEDIARIES).—Section 1816 (42
12 U.S.C. 1395h) is amended as follows:

13 (1) The heading is amended to read as follows:
14 “PROVISIONS RELATING TO THE ADMINISTRATION OF PART A”.

15 (2) Subsection (a) is amended to read as follows:
16 “(a) The administration of this part shall be conducted
17 through contracts with medicare administrative contractors
18 under section 1874A.”.

19 (3) Subsection (b) is repealed.

20 (4) Subsection (c) is amended—

21 (A) by striking paragraph (1); and

22 (B) in each of paragraphs (2)(A) and (3)(A), by
23 striking “agreement under this section” and inserting
24 “contract under section 1874A that provides for mak-
25 ing payments under this part”.

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

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

28 (A) by striking “An agreement with an agency or
29 organization under this section” and inserting “A con-
30 tract with a medicare administrative contractor under
31 section 1874A with respect to the administration of
32 this part”; and

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

36 (7) Subsection (l) is repealed.

1 (c) CONFORMING AMENDMENTS TO SECTION 1842 (RE-
2 LATING TO CARRIERS).—Section 1842 (42 U.S.C. 1395u) is
3 amended as follows:

4 (1) The heading is amended to read as follows:
5 “PROVISIONS RELATING TO THE ADMINISTRATION OF PART B”.

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

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

10 (3) Subsection (b) is amended—

11 (A) by striking paragraph (1);

12 (B) in paragraph (2)—

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

14 (ii) in subparagraph (C), by striking “car-
15 riers” and inserting “medicare administrative con-
16 tractors”; and

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

18 (C) in paragraph (3)—

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

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

25 (iii) in subparagraph (B), in the matter before
26 clause (i), by striking “to the policyholders and
27 subscribers of the carrier” and inserting “to the
28 policyholders and subscribers of the medicare ad-
29 ministrative contractor”;

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

32 (v) in subparagraph (H)—

33 (I) by striking “if it makes determinations
34 or payments with respect to physicians’ serv-
35 ices,”; and

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

14

- 1 (vi) by striking subparagraph (I);
- 2 (vii) in subparagraph (L), by striking the
3 semicolon and inserting a period;
- 4 (viii) in the first sentence, after subparagraph
5 (L), by striking “and shall contain” and all that
6 follows through the period; and
- 7 (ix) in the seventh sentence, by inserting
8 “medicare administrative contractor,” after “car-
9 rier,”; and
- 10 (D) by striking paragraph (5);
- 11 (E) in paragraph (6)(D)(iv), by striking “carrier”
12 and inserting “medicare administrative contractor”;
- 13 (F) in paragraph (7), by striking “the carrier”
14 and inserting “the Secretary” each place it appears.
- 15 (4) Subsection (c) is amended—
- 16 (A) by striking paragraph (1);
- 17 (B) in paragraph (2), by striking “contract under
18 this section which provides for the disbursement of
19 funds, as described in subsection (a)(1)(B),” and in-
20 serting “contract under section 1874A that provides for
21 making payments under this part shall provide that the
22 medicare administrative contractor”;
- 23 (C) in paragraph (3)(A), by striking “subsection
24 (a)(1)(B)” and inserting “section 1874A(a)(3)(B)”;
- 25 (D) in paragraph (4), by striking “carrier” and in-
26 serting “medicare administrative contractor”;
- 27 (E) in paragraph (5), by striking “contract under
28 this section which provides for the disbursement of
29 funds, as described in subsection (a)(1)(B), shall re-
30 quire the carrier” and “carrier responses” and insert-
31 ing “contract under section 1874A that provides for
32 making payments under this part shall require the
33 medicare administrative contractor” and “contractor
34 responses”, respectively; and
- 35 (F) by striking paragraph (6).
- 36 (5) Subsections (d), (e), and (f) are repealed.

1 (6) Subsection (g) is amended by striking “carrier or
2 carriers” and inserting “medicare administrative contractor
3 or contractors”.

4 (7) Subsection (h) is amended—

5 (A) in paragraph (2)—

6 (i) by striking “Each carrier having an agree-
7 ment with the Secretary under subsection (a)” and
8 inserting “The Secretary”; and

9 (ii) by striking “Each such carrier” and in-
10 sserting “The Secretary”;

11 (B) in paragraph (3)(A)—

12 (i) by striking “a carrier having an agreement
13 with the Secretary under subsection (a)” and in-
14 sserting “medicare administrative contractor having
15 a contract under section 1874A that provides for
16 making payments under this part”; and

17 (ii) by striking “such carrier” and inserting
18 “such contractor”;

19 (C) in paragraph (3)(B)—

20 (i) by striking “a carrier” and inserting “a
21 medicare administrative contractor” each place it
22 appears; and

23 (ii) by striking “the carrier” and inserting
24 “the contractor” each place it appears; and

25 (D) in paragraphs (5)(A) and (5)(B)(iii), by strik-
26 ing “carriers” and inserting “medicare administrative
27 contractors” each place it appears.

28 (8) Subsection (l) is amended—

29 (A) in paragraph (1)(A)(iii), by striking “carrier”
30 and inserting “medicare administrative contractor”;
31 and

32 (B) in paragraph (2), by striking “carrier” and in-
33 sserting “medicare administrative contractor”.

34 (9) Subsection (p)(3)(A) is amended by striking “car-
35 rier” and inserting “medicare administrative contractor”.

36 (10) Subsection (q)(1)(A) is amended by striking “car-
37 rier”.

1 (d) EFFECTIVE DATE; TRANSITION RULE.—

2 (1) EFFECTIVE DATE.—Except as otherwise provided
3 in this subsection, the amendments made by this section
4 shall take effect on October 1, 2003, and the Secretary of
5 Health and Human Services is authorized to take such
6 steps before such date as may be necessary to implement
7 such amendments on a timely basis.

8 (2) GENERAL TRANSITION RULES.—The Secretary
9 shall take such steps as are necessary to provide for an ap-
10 propriate transition from contracts under section 1816 and
11 section 1842 of the Social Security Act (42 U.S.C. 1395h,
12 1395u) to contracts under section 1874A, as added by sub-
13 section (a)(1), consistent with the requirements under such
14 section to competitively bid all contracts within 5 years
15 after the effective date in paragraph (1).

16 (3) AUTHORIZING CONTINUATION OF MIP FUNCTIONS
17 UNDER CURRENT CONTRACTS AND AGREEMENTS AND
18 UNDER ROLLOVER CONTRACTS.—The provisions contained
19 in the exception in section 1893(d)(2) of the Social Secu-
20 rity Act (42 U.S.C. 1395ddd(d)(2)) shall continue to apply
21 notwithstanding the amendments made by this section, and
22 any reference in such provisions to an agreement or con-
23 tract shall be deemed to include a contract under section
24 1874A of such Act, as inserted by subsection (a)(1), that
25 continues the activities referred to in such provisions.

26 (e) REFERENCES.—On and after the effective date pro-
27 vided under subsection (d), any reference to a fiscal inter-
28 mediary or carrier under title XI or XVIII of the Social Secu-
29 rity Act (or any regulation, manual instruction, interpretative
30 rule, statement of policy, or guideline issued to carry out such
31 titles) shall be deemed a reference to an appropriate medicare
32 administrative contractor (as provided under section 1874A of
33 the Social Security Act).

34 **SEC. 5. PROVIDER EDUCATION AND TECHNICAL ASSIST-**
35 **ANCE.**

36 (a) COORDINATION OF EDUCATION FUNDING.—

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

3 “PROVIDER EDUCATION AND TECHNICAL ASSISTANCE
4 “SEC. 1889. (a) COORDINATION OF EDUCATION FUND-
5 ING.—The Secretary shall coordinate the educational activities
6 provided through medicare contractors (as defined in sub-
7 section (i), including under section 1893) in order to maximize
8 the effectiveness of Federal education efforts for providers of
9 services and suppliers.”.

10 (2) EFFECTIVE DATE.—The amendment made by
11 paragraph (1) shall take effect on the date of the enact-
12 ment of this Act.

13 (3) REPORT.—Not later than October 1, 2002, the
14 Secretary of Health and Human Services shall submit to
15 Congress a report that includes a description and evalua-
16 tion of the steps taken to coordinate the funding of pro-
17 vider education under section 1889(a) of the Social Secu-
18 rity Act, as added by paragraph (1).

19 (b) INCENTIVES TO IMPROVE CONTRACTOR PERFORM-
20 ANCE.—

21 (1) IN GENERAL.—Section 1874A, as added by section
22 4(a)(1), is amended by adding at the end the following new
23 subsection:

24 “(e) INCENTIVES TO IMPROVE CONTRACTOR PERFORM-
25 ANCE IN PROVIDER EDUCATION AND OUTREACH.—

26 “(1) METHODOLOGY TO MEASURE CONTRACTOR
27 ERROR RATES.—In order to give medicare administrative
28 contractors an incentive to implement effective education
29 and outreach programs for providers of services and sup-
30 pliers, the Secretary shall, in consultation with representa-
31 tives of providers and suppliers, develop and implement by
32 October 1, 2003, a methodology to measure the specific
33 claims payment error rates of such contractors in the proc-
34 essing or reviewing of medicare claims.

35 “(2) IDENTIFICATION OF BEST PRACTICES.—The Sec-
36 retary shall identify the best practices developed by indi-
37 vidual medicare administrative contractors for educating

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

3 (2) REPORT.—Not later than October 1, 2003, the
4 Secretary of Health and Human Services shall submit to
5 Congress a report that describes how the Secretary intends
6 to use the methodology developed under section
7 1874A(e)(1) of the Social Security Act, as added by para-
8 graph (1), in assessing medicare contractor performance in
9 implementing effective education and outreach programs,
10 including whether to use such methodology as the basis for
11 performance bonuses. The report shall include an analysis
12 of the sources of identified errors and potential changes in
13 systems of contractors and rules of the Secretary that could
14 reduce claims error rates.

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

17 (1) IN GENERAL.—Section 1874A, as added by section
18 4(a)(1) and as amended by subsection (b), is further
19 amended by adding at the end the following new sub-
20 section:

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

22 “(1) CONTRACTOR RESPONSIBILITY.—Each medicare
23 administrative contractor shall, for those providers of serv-
24 ices and suppliers which submit claims to the contractor for
25 claims processing—

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

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

33 “(C) maintain a system for identifying (and dis-
34 closing, upon request) who provides the information re-
35 ferred to in subparagraphs (A) and (B); and

36 “(D) monitor the accuracy, consistency, and time-
37 liness of the information so provided.

1 “(2) EVALUATION.—In conducting evaluations of indi-
2 vidual medicare administrative contractors, the Secretary
3 shall take into account the results of the monitoring con-
4 ducted under paragraph (1)(D). The Secretary shall, in
5 consultation with organizations representing providers of
6 services and suppliers, establish standards relating to the
7 accuracy, consistency, and timeliness of the information so
8 provided.”.

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

11 (d) IMPROVED PROVIDER EDUCATION AND TRAINING.—

12 (1) IN GENERAL.—Section 1889, as added by sub-
13 section (a), is amended by adding at the end the following
14 new subsections:

15 “(b) ENHANCED EDUCATION AND TRAINING.—

16 “(1) ADDITIONAL RESOURCES.—For each of fiscal
17 years 2003 and 2004, there are authorized to be appro-
18 priated to the Secretary (in appropriate part from the Fed-
19 eral Hospital Insurance Trust Fund and the Federal Sup-
20 plementary Medical Insurance Trust Fund) \$10,000,000 .

21 “(2) USE.—The funds made available under para-
22 graph (1) shall be used to increase the conduct by medicare
23 contractors of education and training of providers of serv-
24 ices and suppliers regarding billing, coding, and other ap-
25 propriate items.

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

28 “(1) IN GENERAL.—Insofar as a medicare contractor
29 conducts education and training activities, it shall tailor
30 such activities to meet the special needs of small providers
31 of services or suppliers (as defined in paragraph (2)).

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

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

1 “(B) a supplier with fewer than 10 full-time-equiv-
2 alent employees.”.

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

5 (e) REQUIREMENT TO MAINTAIN INTERNET SITES.—

6 (1) IN GENERAL.—Section 1889, as added by sub-
7 section (a) and as amended by subsection (d), is further
8 amended by adding at the end the following new sub-
9 section:

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

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

16 “(2) includes other published materials of the con-
17 tractor,

18 that relate to providers of services and suppliers under the pro-
19 grams under this title (and title XI insofar as it relates to such
20 programs).”.

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

23 (f) ADDITIONAL PROVIDER EDUCATION PROVISIONS.—

24 (1) IN GENERAL.—Section 1889, as added by sub-
25 section (a) and as amended by subsections (d) and (e), is
26 further amended by adding at the end the following new
27 subsections:

28 “(e) ENCOURAGEMENT OF PARTICIPATION IN EDUCATION
29 PROGRAM ACTIVITIES.—A medicare contractor may not use a
30 record of attendance at (or failure to attend) educational activi-
31 ties or other information gathered during an educational pro-
32 gram conducted under this section or otherwise by the Sec-
33 retary to select or track providers of services or suppliers for
34 the purpose of conducting any type of audit or prepayment re-
35 view.

1 “(f) CONSTRUCTION.—Nothing in this section or section
2 1893(g) shall be construed as providing for disclosure by a
3 medicare contractor—

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

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

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

11 “(1) A medicare administrative contractor with a con-
12 tract under section 1874A, including a fiscal intermediary
13 with a contract under section 1816 and a carrier with a
14 contract under section 1842.

15 “(2) An eligible entity with a contract under section
16 1893.

17 Such term does not include, with respect to activities of a spe-
18 cific provider of services or supplier an entity that has no au-
19 thority under this title or title IX with respect to such activities
20 and such provider of services or supplier.”.

21 (2) EFFECTIVE DATE.—The amendment made by
22 paragraph (1) shall take effect on the date of the enact-
23 ment of this Act.

24 **SEC. 6. SMALL PROVIDER TECHNICAL ASSISTANCE**
25 **DEMONSTRATION PROGRAM.**

26 (a) ESTABLISHMENT.—

27 (1) IN GENERAL.—The Secretary of Health and
28 Human Services shall establish a demonstration program
29 (in this section referred to as the “demonstration pro-
30 gram”) under which technical assistance described in para-
31 graph (2) is made available, upon request and on a vol-
32 untary basis, to small providers of services or suppliers in
33 order to improve compliance with the applicable require-
34 ments of the programs under medicare program under title
35 XVIII of the Social Security Act (including provisions of
36 title XI of such Act insofar as they relate to such title and

1 are not administered by the Office of the Inspector General
2 of the Department of Health and Human Services).

3 (2) FORMS OF TECHNICAL ASSISTANCE.—The tech-
4 nical assistance described in this paragraph is—

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

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

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

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

15 (B) a supplier with fewer than 10 full-time-equiva-
16 lent employees.

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

29 (c) DESCRIPTION OF TECHNICAL ASSISTANCE.—The tech-
30 nical assistance provided under the demonstration program
31 shall include a direct and in-person examination of billing sys-
32 tems and internal controls of small providers of services or sup-
33 pliers to determine program compliance and to suggest more
34 efficient or effective means of achieving such compliance.

35 (d) AVOIDANCE OF RECOVERY ACTIONS FOR PROBLEMS
36 IDENTIFIED AS CORRECTED.—The Secretary of Health and
37 Human Services shall provide that, absent evidence of fraud

1 and notwithstanding any other provision of law, any errors
2 found in a compliance review for a small provider of services
3 or supplier that participates in the demonstration program
4 shall not be subject to recovery action if the technical assist-
5 ance personnel under the program determine that—

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

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

12 (e) GAO EVALUATION.—Not later than 2 years after the
13 date of the date the demonstration program is first imple-
14 mented, the Comptroller General, in consultation with the In-
15 spector General of the Department of Health and Human Serv-
16 ices, shall conduct an evaluation of the demonstration program.
17 The evaluation shall include a determination of whether claims
18 error rates are reduced for small providers of services or sup-
19 pliers who participated in the program and the extent of im-
20 proper payments made as a result of the demonstration pro-
21 gram. The Comptroller General shall submit a report to the
22 Secretary and the Congress on such evaluation and shall in-
23 clude in such report recommendations regarding the continu-
24 ation or extension of the demonstration program.

25 (f) FINANCIAL PARTICIPATION BY PROVIDERS.—The pro-
26 vision of technical assistance to a small provider of services or
27 supplier under the demonstration program is conditioned upon
28 the small provider of services or supplier paying an amount es-
29 timated (and disclosed in advance of a provider's or supplier's
30 participation in the program) to be equal to 25 percent of the
31 cost of the technical assistance.

32 (g) AUTHORIZATION OF APPROPRIATIONS.—There are au-
33 thorized to be appropriated to the Secretary of Health and
34 Human Services (in appropriate part from the Federal Hos-
35 pital Insurance Trust Fund and the Federal Supplementary
36 Medical Insurance Trust Fund) to carry out the demonstration
37 program—

- 1 (1) for fiscal year 2003, \$1,000,000, and
2 (2) for fiscal year 2004, \$6,000,000.

3 **SEC. 7. MEDICARE PROVIDER OMBUDSMAN; MEDICARE**
4 **BENEFICIARY OMBUDSMAN.**

5 (a) MEDICARE PROVIDER OMBUDSMAN.—Section 1868
6 (42 U.S.C. 1395ee) is amended—

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

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

11 (3) in paragraph (1), as so redesignated under para-
12 graph (2), by striking “in this section” and inserting “in
13 this subsection”;

14 (4) by redesignating subsections (b) and (c) as para-
15 graphs (2) and (3), respectively; and

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

17 “(b) MEDICARE PROVIDER OMBUDSMAN.—The Secretary
18 shall appoint a Medicare Provider Ombudsman. The Ombuds-
19 man shall—

20 “(1) provide assistance, on a confidential basis, to pro-
21 viders of services and suppliers with respect to complaints,
22 grievances, and requests for information concerning the
23 programs under this title (including provisions of title XI
24 insofar as they relate to this title and are not administered
25 by the Office of the Inspector General of the Department
26 of Health and Human Services) and in the resolution of
27 unclear or conflicting guidance given by the Secretary and
28 medicare contractors to such providers of services and sup-
29 pliers regarding such programs and provisions and require-
30 ments under this title and such provisions; and

31 “(2) submit recommendations to the Secretary for im-
32 provement in the administration of this title and such pro-
33 visions, including—

34 “(A) recommendations to respond to recurring
35 patterns of confusion in this title and such provisions
36 (including recommendations regarding suspending im-

1 position of sanctions where there is widespread confu-
2 sion in program administration), and

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

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

10 “MEDICARE BENEFICIARY OMBUDSMAN

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

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

17 “(1) receive complaints, grievances, and requests for
18 information submitted by a medicare beneficiary, with re-
19 spect to any aspect of the medicare program;

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

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

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

30 “(3) submit annual reports to Congress and the Sec-
31 retary that describe the activities of the Office and that in-
32 clude such recommendations for improvement in the admin-
33 istration of this title as the Ombudsman determines appro-
34 priate.”.

35 (c) FUNDING.—There are authorized to be appropriated to
36 the Secretary of Health and Human Services (in appropriate
37 part from the Federal Hospital Insurance Trust Fund and the

1 Federal Supplementary Medical Insurance Trust Fund) to
2 carry out the provisions of subsection (b) of section 1868 of the
3 Social Security Act (relating to the Medicare Provider Ombuds-
4 man), as added by subsection (a)(5) and section 1807 of such
5 Act (relating to the Medicare Beneficiary Ombudsman), as
6 added by subsection (b), such sums as are necessary for fiscal
7 year 2002 and each succeeding fiscal year.

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

19 **SEC. 8. PROVIDER APPEALS.**

20 (a) MEDICARE ADMINISTRATIVE LAW JUDGES.—Section
21 1869 (42 U.S.C. 1395ff), as amended by section 521(a) of
22 Medicare, Medicaid, and SCHIP Benefits Improvement and
23 Protection Act of 2000 (114 Stat. 2763A-534), as enacted into
24 law by section 1(a)(6) of Public Law 106-554, is amended by
25 adding at the end the following new subsection:

26 “(g) MEDICARE ADMINISTRATIVE LAW JUDGES.—

27 “(1) TRANSITION PLAN.—Not later than October 1,
28 2003, the Commissioner of Social Security and the Sec-
29 retary shall develop and implement a plan under which the
30 functions of administrative law judges responsible for hear-
31 ing cases under this title (and related provisions in title XI)
32 shall be transferred from the responsibility of the Commis-
33 sioner and the Social Security Administration to the Sec-
34 retary and the Department of Health and Human Services.
35 The plan shall include recommendations with respect to—

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

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

7 Nothing in this subsection shall be construed as affecting
8 the independence of administrative law judges from the De-
9 partment of Health and Human Services and from medi-
10 care contractors in carrying out their responsibilities for
11 hearing and deciding cases.

12 “(2) INCREASED FINANCIAL SUPPORT.—In addition to
13 any amounts otherwise appropriated, there are authorized
14 to be appropriated (in appropriate part from the Federal
15 Hospital Insurance Trust Fund and the Federal Supple-
16 mentary Medical Insurance Trust Fund) to the Secretary
17 to increase the number of administrative law judges de-
18 scribed in paragraph (1) and to improve education and
19 training for such judges and their staffs in carrying out
20 functions under this title, \$5,000,000 for fiscal year 2003
21 and such sums as are necessary for fiscal year 2004 and
22 each subsequent fiscal year.

23 “(3) SUBMITTAL OF PLAN TO CONGRESS AND GAO;
24 REPORT OF GAO.—Not later than July 1, 2003, the Sec-
25 retary shall submit to the Committee on Ways and Means
26 of the House of Representatives, the Committee on Finance
27 of the Senate, and the Comptroller General of the United
28 States the terms of the plan developed under paragraph
29 (1). No later than September 1, 2003, the Comptroller
30 General shall submit to such Committees a report con-
31 taining an evaluation of the terms of such plan.”.

32 (b) PROCESS FOR EXPEDITED ACCESS TO JUDICIAL RE-
33 VIEW.—

34 (1) IN GENERAL.—Section 1869(b) (42 U.S.C.
35 1395ff(b)) as amended by Medicare, Medicaid, and SCHIP
36 Benefits Improvement and Protection Act of 2000 (114

1 Stat. 2763A-534), as enacted into law by section 1(a)(6)
2 of Public Law 106-554, is amended—

3 (A) in paragraph (1)(A), by inserting “, subject to
4 paragraph (2),” before “to judicial review of the Sec-
5 retary’s final decision”; and

6 (B) by adding at the end the following new para-
7 graph:

8 “(2) EXPEDITED ACCESS TO JUDICIAL REVIEW.—

9 “(A) IN GENERAL.—The Secretary shall establish
10 a process under which a provider of services or supplier
11 that furnishes an item or service or a beneficiary who
12 has filed an appeal under paragraph (1) (other than an
13 appeal filed under paragraph (1)(F)) may obtain access
14 to judicial review when a review panel (described in
15 subparagraph (D)), on its own motion or at the request
16 of the appellant, determines that it does not have the
17 authority to decide the question of law or regulation
18 relevant to the matters in controversy and that there
19 is no material issue of fact in dispute. The appellant
20 may make such request only once with respect to a
21 question of law or regulation in a case of an appeal.

22 “(B) PROMPT DETERMINATIONS.—If, after or co-
23 incident with appropriately filing a request for an ad-
24 ministrative hearing, the appellant requests a deter-
25 mination by the appropriate review panel that no re-
26 view panel has the authority to decide the question of
27 law or regulations relevant to the matters in con-
28 troversy and that there is no material issue of fact in
29 dispute and if such request is accompanied by the doc-
30 uments and materials as the appropriate review panel
31 shall require for purposes of making such determina-
32 tion, such review panel shall make a determination on
33 the request in writing within 60 days after the date
34 such review panel receives the request and such accom-
35 panying documents and materials. Such a determina-
36 tion by such review panel shall be considered a final de-
37 cision and not subject to review by the Secretary.

1 “(C) ACCESS TO JUDICIAL REVIEW.—
2 “(i) IN GENERAL.—If the appropriate review
3 panel—
4 “(I) determines that there are no material
5 issues of fact in dispute and that the only issue
6 is one of law or regulation that no review panel
7 has the authority to decide; or
8 “(II) fails to make such determination
9 within the period provided under subparagraph
10 (B);
11 then the appellant may bring a civil action as de-
12 scribed in this subparagraph.
13 “(ii) DEADLINE FOR FILING.—Such action
14 shall be filed, in the case described in—
15 “(I) clause (i)(I), within 60 days of date
16 of the determination described in such subpara-
17 graph; or
18 “(II) clause (i)(II), within 60 days of the
19 end of the period provided under subparagraph
20 (B) for the determination.
21 “(iii) VENUE.—Such action shall be brought
22 in the district court of the United States for the ju-
23 dicial district in which the appellant is located (or,
24 in the case of an action brought jointly by more
25 than one applicant, the judicial district in which
26 the greatest number of applicants are located) or in
27 the district court for the District of Columbia.
28 “(iv) INTEREST ON AMOUNTS IN CON-
29 TROVERSY.—Where a provider of services or sup-
30 plier seeks judicial review pursuant to this para-
31 graph, the amount in controversy shall be subject
32 to annual interest beginning on the first day of the
33 first month beginning after the 60-day period as
34 determined pursuant to clause (ii) and equal to the
35 rate of interest on obligations issued for purchase
36 by the Federal Hospital Insurance Trust Fund for
37 the month in which the civil action authorized

1 under this paragraph is commenced, to be awarded
2 by the reviewing court in favor of the prevailing
3 party. No interest awarded pursuant to the pre-
4 ceding sentence shall be deemed income or cost for
5 the purposes of determining reimbursement due
6 providers of services or suppliers under this Act.

7 “(D) REVIEW PANELS.—For purposes of this sub-
8 section, a ‘review panel’ is an administrative law judge,
9 the Departmental Appeals Board, a qualified inde-
10 pendent contractor (as defined in subsection (c)(2)), or
11 an entity designated by the Secretary for purposes of
12 making determinations under this paragraph.”.

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

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

20 (3) EFFECTIVE DATE.—The amendments made by
21 this subsection shall apply to appeals filed on or after Octo-
22 ber 1, 2002.

23 (c) REQUIRING FULL AND EARLY PRESENTATION OF EVI-
24 DENCE.—

25 (1) IN GENERAL.—Section 1869(b) (42 U.S.C.
26 1395ff(b)), as amended by Medicare, Medicaid, and SCHIP
27 Benefits Improvement and Protection Act of 2000 (114
28 Stat. 2763A–534), as enacted into law by section 1(a)(6)
29 of Public Law 106–554, and as amended by subsection (b),
30 is further amended by adding at the end the following new
31 paragraph:

32 “(3) REQUIRING FULL AND EARLY PRESENTATION OF
33 EVIDENCE BY PROVIDERS.—A provider of services or sup-
34 plier may not introduce evidence in any appeal under this
35 section that was not presented at the reconsideration con-
36 ducted by the qualified independent contractor under sub-
37 section (c), unless there is good cause which precluded the

1 introduction of such evidence at or before that reconsider-
2 ation.”.

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

5 **SEC. 9. RECOVERY OF OVERPAYMENTS AND PREPAY-**
6 **MENT REVIEW; ENROLLMENT OF PRO-**
7 **VIDERS.**

8 (a) RECOVERY OF OVERPAYMENTS AND PREPAYMENT RE-
9 VIEW.—Section 1893 (42 U.S.C. 1395ddd) is amended by add-
10 ing at the end the following new subsections:

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

13 “(1) USE OF REPAYMENT PLANS.—

14 “(A) IN GENERAL.—If the repayment, within 30
15 days by a provider of services or supplier, of an over-
16 payment under this title would constitute a hardship
17 (as defined in subparagraph (B)), subject to subpara-
18 graph (C), the Secretary shall enter into a plan (which
19 meets terms and conditions determined to be appro-
20 priate by the Secretary) with the provider of services
21 or supplier for the offset or repayment of such overpay-
22 ment over a period of not longer than 3 years, or in
23 the case of extreme hardship (as determined by the
24 Secretary) over a period of not longer than 5 years. In-
25 terest shall accrue on the balance through the period
26 of repayment.

27 “(B) HARDSHIP.—

28 “(i) IN GENERAL.—For purposes of subpara-
29 graph (A), the repayment of an overpayment (or
30 overpayments) within 30 days is deemed to con-
31 stitute a hardship if—

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

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

7 “(ii) RULE OF APPLICATION.—The Secretary
8 shall establish rules for the application of this sub-
9 paragraph in the case of a provider of services or
10 supplier that was not paid under this title during
11 the previous year or was paid under this title only
12 during a portion of that year.

13 “(iii) TREATMENT OF PREVIOUS OVERPAY-
14 MENTS.—If a provider of services or supplier has
15 entered into a repayment plan under subparagraph
16 (A) with respect to a specific overpayment amount,
17 such payment amount under the repayment plan
18 shall not be taken into account under clause (i)
19 with respect to subsequent overpayment amounts.

20 “(C) EXCEPTIONS.—Subparagraph (A) shall not
21 apply if the Secretary has reason to suspect that the
22 provider of services or supplier may file for bankruptcy
23 or otherwise cease to do business or if there is an indi-
24 cation of fraud or abuse committed against the pro-
25 gram.

26 “(D) IMMEDIATE COLLECTION IF VIOLATION OF
27 REPAYMENT PLAN.—If a provider of services or sup-
28 plier fails to make a payment in accordance with a re-
29 payment plan under this paragraph, the Secretary may
30 immediately seek to offset or otherwise recover the
31 total balance outstanding (including applicable interest)
32 under the repayment plan.

33 “(2) LIMITATION ON RECOUPMENT UNTIL DETER-
34 MINATION BY QUALIFIED INDEPENDENT CONTRACTOR.—

35 “(A) IN GENERAL.—In the case of a provider of
36 services or supplier that is determined to have received
37 an overpayment under this title and that seeks a recon-

1 sideration by a qualified independent contractor on
2 such determination under section 1869(b)(1), the Sec-
3 retary may not take any action (or authorize any other
4 person, including any medicare contractor, as defined
5 in paragraph (9)) to recoup the overpayment until the
6 date the decision on the reconsideration has been ren-
7 dered.

8 “(B) COLLECTION WITH INTEREST.—Insofar as
9 the determination on such appeal is against the pro-
10 vider of services or supplier, interest on the overpay-
11 ment shall accrue on and after the date of the original
12 notice of overpayment. Insofar as such determination
13 against the provider of services or supplier is later re-
14 versed, the Secretary shall provide for repayment of the
15 amount recouped plus interest at the same rate as
16 would apply under the previous sentence for the period
17 in which the amount was recouped.

18 “(3) STANDARDIZATION OF RANDOM PREPAYMENT RE-
19 VIEW.—

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

26 “(B) CONSTRUCTION.—Nothing in subparagraph
27 (A) shall be construed as preventing the denial of pay-
28 ments for claims actually reviewed under a random pre-
29 payment review.

30 “(4) LIMITATION ON USE OF EXTRAPOLATION.—A
31 medicare contractor may not use extrapolation to determine
32 overpayment amounts to be recovered by recoupment, off-
33 set, or otherwise unless—

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

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

4 “(5) PROVISION OF SUPPORTING DOCUMENTATION.—
5 In the case of a provider of services or supplier with respect
6 to which amounts were previously overpaid, a medicare con-
7 tractor may request the periodic production of records or
8 supporting documentation for a limited sample of sub-
9 mitted claims to ensure that the previous practice is not
10 continuing.

11 “(6) CONSENT SETTLEMENT REFORMS.—

12 “(A) IN GENERAL.—The Secretary may use a con-
13 sent settlement (as defined in subparagraph (D)) to
14 settle a projected overpayment.

15 “(B) OPPORTUNITY TO SUBMIT ADDITIONAL IN-
16 FORMATION BEFORE CONSENT SETTLEMENT OFFER.—
17 Before offering a provider of services or supplier a con-
18 sent settlement, the Secretary shall—

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

24 “(ii) provide for a 45-day period during which
25 the provider of services or supplier may furnish ad-
26 ditional information concerning the medical records
27 for the claims that had been reviewed.

28 “(C) CONSENT SETTLEMENT OFFER.—The Sec-
29 retary shall review any additional information furnished
30 by the provider of services or supplier under subpara-
31 graph (B)(ii). Taking into consideration such informa-
32 tion, the Secretary shall determine if there still appears
33 to be an overpayment. If so, the Secretary—

34 “(i) shall provide notice of such determination
35 to the provider of services or supplier, including an
36 explanation of the reason for such determination;
37 and

1 “(ii) in order to resolve the overpayment, may
2 offer the provider of services or supplier—

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

5 “(II) a consent settlement.

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

9 “(D) CONSENT SETTLEMENT DEFINED.—For pur-
10 poses of this paragraph, the term ‘consent settlement’
11 means an agreement between the Secretary and a pro-
12 vider of services or supplier whereby both parties agree
13 to settle a projected overpayment based on less than a
14 statistically valid sample of claims and the provider of
15 services or supplier agrees not to appeal the claims in-
16 volved.

17 “(7) LIMITATIONS ON NON-RANDOM PREPAYMENT RE-
18 VIEW.—

19 “(A) LIMITATION ON INITIATION OF NON-RAN-
20 DOM PREPAYMENT REVIEW.—A medicare con-
21 tractor may not initiate non-random prepayment
22 review of a provider of services or supplier based on
23 the initial identification by that provider of services
24 or supplier of an improper billing practice unless
25 there is a sustained or high level of payment error
26 (as defined in paragraph (4)(A)).

27 “(B) TERMINATION OF NON-RANDOM PREPAY-
28 MENT REVIEW.—The Secretary shall issue regula-
29 tions relating to the termination, including termi-
30 nation dates, of non-random prepayment review.
31 Such regulations may vary such a termination date
32 based upon the differences in the circumstances
33 triggering prepayment review.

34 “(8) PAYMENT AUDITS.—

35 “(A) WRITTEN NOTICE FOR POST-PAYMENT AU-
36 DITS.—Subject to subparagraph (C), if a medicare con-
37 tractor decides to conduct a post-payment audit of a

1 provider of services or supplier under this title, the con-
2 tractor shall provide the provider of services or supplier
3 with written notice of the intent to conduct such an
4 audit.

5 “(B) EXPLANATION OF FINDINGS FOR ALL AU-
6 DITS.—Subject to subparagraph (C), if a medicare con-
7 tractor audits a provider of services or supplier under
8 this title, the contractor shall provide for an exit con-
9 ference with the provider or supplier during which the
10 contractor shall—

11 “(i) give the provider of services or supplier a
12 full review and explanation of the findings of the
13 audit in a manner that is understandable to the
14 provider of services or supplier and permits the de-
15 velopment of an appropriate corrective action plan;

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

18 “(iii) give the provider of services or supplier
19 an opportunity to provide additional information to
20 the contractor; and

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

24 “(C) EXCEPTION.—Subparagraphs (A) and (B)
25 shall not apply if the provision of notice or findings
26 would compromise pending law enforcement activities
27 or reveal findings of law enforcement-related audits.

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

29 “(A) MEDICARE CONTRACTOR.—The term ‘medi-
30 care contractor’ has the meaning given such term in
31 section 1889(g).

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

36 “(g) NOTICE OF OVER-UTILIZATION OF CODES.—The
37 Secretary shall establish a process under which the Secretary

1 provides for notice to classes of providers of services and sup-
2 pliers served by the contractor in cases in which the contractor
3 has identified that particular billing codes may be overutilized
4 by that class of providers of services or suppliers under the pro-
5 grams under this title (or provisions of title XI insofar as they
6 relate to such programs).”.

7 (b) PROVIDER ENROLLMENT PROCESS; RIGHT OF AP-
8 PEAL.—

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

11 (A) by adding at the end of the heading the fol-
12 lowing: “; ENROLLMENT PROCESSES”; and

13 (B) by adding at the end the following new sub-
14 section:

15 “(j) ENROLLMENT PROCESS FOR PROVIDERS OF SERV-
16 ICES AND SUPPLIERS.—

17 “(1) IN GENERAL.—The Secretary shall establish by
18 regulation a process for the enrollment of providers of serv-
19 ices and suppliers under this title.

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

21 “(A) a method by which providers of services and
22 suppliers whose application to enroll (or, if applicable,
23 to renew enrollment) are denied are provided a mecha-
24 nism to appeal such denial; and

25 “(B) prompt deadlines for actions on applications
26 for enrollment (and, if applicable, renewal of enroll-
27 ment) and for consideration of appeals.”.

28 (2) EFFECTIVE DATE.—The Secretary of Health and
29 Human Services shall provide for the establishment of the
30 enrollment and appeal process under the amendment made
31 by paragraph (1) within 6 months after the date of the en-
32 actment of this Act.

33 (c) PROCESS FOR CORRECTION OF MINOR ERRORS AND
34 OMISSIONS ON CLAIMS WITHOUT PURSUING APPEALS PROC-
35 ESS.—The Secretary of Health and Human Services shall de-
36 velop, in consultation with appropriate medicare contractors (as
37 defined in section 1889(g) of the Social Security Act, as in-

1 serted by section 5(f)(1)) and representatives of providers of
2 services and suppliers, a process whereby, in the case of minor
3 errors or omissions that are detected in the submission of
4 claims under the programs under title XVIII of such Act, a
5 provider of services or supplier is given an opportunity to cor-
6 rect such an error or omission without the need to initiate an
7 appeal. Such process shall include the ability to resubmit cor-
8 rected claims.

9 **SEC. 10. BENEFICIARY OUTREACH DEMONSTRATION**
10 **PROGRAM.**

11 (a) IN GENERAL.—The Secretary of Health and Human
12 Services shall establish a demonstration program (in this sec-
13 tion referred to as the “demonstration program”) under which
14 medicare specialists employed by the Department of Health and
15 Human Services provide advice and assistance to medicare
16 beneficiaries regarding the medicare program at the location of
17 existing local offices of the Social Security Administration.

18 (b) LOCATIONS.—

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

24 (2) ASSISTANCE FOR RURAL BENEFICIARIES.—The
25 Secretary shall provide for the selection of at least 2 rural
26 areas to participate in the demonstration program. In con-
27 ducting the demonstration program in such rural areas, the
28 Secretary shall provide for medicare specialists to travel
29 among local offices in a rural area on a scheduled basis.

30 (c) DURATION.—The demonstration program shall be con-
31 ducted over a 3-year period.

32 (d) EVALUATION AND REPORT.—

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

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

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

4 (2) REPORT.—The Secretary shall submit to Congress
5 a report on such evaluation and shall include in such report
6 recommendations regarding the feasibility of permanently
7 out-stationing medicare specialists at local offices of the So-
8 cial Security Administration.

9 **SEC. 11. POLICY DEVELOPMENT REGARDING EVALUA-**
10 **TION AND MANAGEMENT (E & M) DOCU-**
11 **MENTATION GUIDELINES.**

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

17 (1) has developed the guidelines in collaboration with
18 practicing physicians and provided for an assessment of the
19 proposed guidelines by the physician community;

20 (2) has established a plan that contains specific goals,
21 including a schedule, for improving the use of such guide-
22 lines;

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

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

28 (5) has conducted appropriate outreach to physicians
29 for education and training with respect to the guidelines.

30 The Secretary shall make changes to the manner in which ex-
31 isting evaluation and management documentation guidelines
32 are implemented to reduce paperwork burdens on physicians.

33 (b) PILOT PROJECTS TO TEST EVALUATION AND MAN-
34 AGEMENT DOCUMENTATION GUIDELINES.—

35 (1) LENGTH AND CONSULTATION.—Each pilot project
36 under this subsection shall—

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

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

8 (2) RANGE OF PILOT PROJECTS.—Of the pilot projects
9 conducted under this subsection—

10 (A) at least one shall focus on a peer review meth-
11 od by physicians (not employed by a medicare con-
12 tractor) which evaluates medical record information for
13 claims submitted by physicians identified as statistical
14 outliers relative to definitions published in the Current
15 Procedures Terminology (CPT) code book of the Amer-
16 ican Medical Association;

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

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

23 (D) at least one shall be conducted in a setting
24 where physicians bill under physicians services in teach-
25 ing settings and at one shall be conducted in a setting
26 other than a teaching setting.

27 (3) BANNING OF TARGETING OF PILOT PROJECT PAR-
28 TICIPANTS.—Data collected under this subsection shall not
29 be used as the basis for overpayment demands or post-pay-
30 ment audits.

31 (4) STUDY OF IMPACT.—Each pilot project shall ex-
32 amine the effect of the modified evaluation and manage-
33 ment documentation guidelines on—

34 (A) different types of physician practices, includ-
35 ing those with fewer than 10 full-time-equivalent em-
36 ployees (including physicians); and

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

3 (c) OBJECTIVES FOR EVALUATION AND MANAGEMENT
4 GUIDELINES.—The objectives for modified evaluation and man-
5 agement documentation guidelines developed by the Secretary
6 shall be to—

7 (1) enhance clinically relevant documentation needed
8 to code accurately and assess coding levels accurately;

9 (2) decrease the level of non-clinically pertinent and
10 burdensome documentation time and content in the physi-
11 cian's medical record;

12 (3) increase accuracy by reviewers; and

13 (4) educate both physicians and reviewers.

14 (d) STUDY OF SIMPLER, ALTERNATIVE SYSTEMS OF DOC-
15 UMENTATION FOR PHYSICIAN CLAIMS.—

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

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

21 (A) the development of a simpler, alternative sys-
22 tem of requirements for documentation accompanying
23 claims for evaluation and management physician serv-
24 ices for which payment is made under title XVIII of
25 the Social Security Act; and

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

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

33 (4) APPLICATION OF HIPAA UNIFORM CODING RE-
34 QUIREMENTS.—In developing an alternative system under
35 paragraph (2), the Secretary shall consider requirements of
36 administrative simplification under part C of title XI of the
37 Social Security Act.

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

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

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

16 (f) DEFINITIONS.—In this section—

17 (1) the term “rural area” has the meaning given that
18 term in section 1886(d)(2)(D) of the Social Security Act,
19 42 U.S.C. 1395ww(d)(2)(D); and

20 (2) the term “teaching settings” are those settings de-
21 scribed in section 415.150 of title 42, Code of Federal Reg-
22 ulations.

23 **SEC. 12. IMPROVEMENT IN OVERSIGHT OF TECH-**
24 **NOLOGY AND COVERAGE.**

25 (a) IMPROVED COORDINATION BETWEEN FDA AND CMS
26 ON COVERAGE OF BREAKTHROUGH MEDICAL DEVICES.—

27 (1) IN GENERAL.—Upon request by an applicant and
28 to the extent feasible (as determined by the Secretary of
29 Health and Human Services), the Secretary shall, in the
30 case of a class III medical device that is subject to pre-
31 market approval under section 515 of the Federal Food,
32 Drug, and Cosmetic Act, coordinate reviews of coverage de-
33 cisions under title XVIII of the Social Security Act with
34 the review for application for premarket approval conducted
35 by the Food and Drug Administration under such section.
36 Such coordination shall include the sharing of appropriate
37 information.

1 (2) PUBLICATION OF PLAN.—Not later than 6 months
2 after the date of the enactment of this Act, the Secretary
3 shall submit to appropriate Committees of Congress a re-
4 port that contains the plan for improving such coordination
5 and for shortening the time lag between the premarket ap-
6 proval by the Food and Drug Administration and coding
7 and coverage decisions by the Centers for Medicare & Med-
8 icaid Services.

9 (3) CONSTRUCTION.—Nothing in this subsection shall
10 be construed as changing the criteria for coverage of a
11 medical device under title XVIII of the Social Security Act
12 nor premarket approval by the Food and Drug Administra-
13 tion.

14 (b) COUNCIL FOR TECHNOLOGY AND INNOVATION.—

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

19 (2) COMPOSITION.—The Council shall be composed of
20 senior CMS staff and clinicians and shall be chaired by the
21 Executive Coordinator for Technology and Innovation (ap-
22 pointed or designated under paragraph (4)).

23 (3) DUTIES.—The Council shall coordinate the activi-
24 ties of coverage, coding, and payment processes under title
25 XVIII of the Social Security Act with respect to new tech-
26 nologies and procedures, including new drug therapies, and
27 shall coordinate the exchange of information on new tech-
28 nologies between CMS and other entities that make similar
29 decisions.

30 (4) EXECUTIVE COORDINATOR FOR TECHNOLOGY AND
31 INNOVATION.—The Secretary shall appoint (or designate) a
32 noncareer appointee (as defined in section 3132(a)(7) of
33 title 5, United States Code) who shall serve as the Execu-
34 tive Coordinator for Technology and Innovation. Such exec-
35 utive coordinator shall report to the Administrator of CMS,
36 shall chair the Council, shall oversee the execution of its
37 duties, and shall serve as a single point of contact for out-

1 side groups and entities regarding the coverage, coding,
2 and payment processes under title XVIII of the Social Se-
3 curity Act.

4 (c) GAO STUDY ON IMPROVEMENTS IN EXTERNAL DATA
5 COLLECTION FOR USE IN THE MEDICARE INPATIENT PAY-
6 MENT SYSTEM.—

7 (1) STUDY.—The Comptroller General of the United
8 States shall conduct a study that analyzes which external
9 data can be collected in a shorter time frame by the Cen-
10 ters For Medicare & Medicaid Services for use in com-
11 puting payments for inpatient hospital services. The study
12 may include an evaluation of the feasibility and appro-
13 priateness of using of quarterly samples or special surveys
14 or any other methods. The study shall include an analysis
15 of whether other executive agencies, such as the Bureau of
16 Labor Statistics in the Department of Commerce, are best
17 suited to collect this information.

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

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

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

25 (A) in subsection (a)(1)—

26 (i) in subparagraph (R), by striking “and” at
27 the end;

28 (ii) in subparagraph (S), by striking the period
29 at the end and inserting “, and”; and

30 (iii) by inserting after subparagraph (S) the
31 following new subparagraph:

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

1 (B) by adding at the end of subsection (b) the fol-
2 lowing new paragraph:

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

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

14 “(C) A civil money penalty under this paragraph shall be
15 imposed and collected in the same manner as civil money pen-
16 alties under subsection (a) of section 1128A are imposed and
17 collected under that section.”.

18 (2) EFFECTIVE DATE.—The amendments made by
19 this paragraph (1) shall apply to hospitals as of July 1,
20 2002.

21 (e) IOM STUDY ON LOCAL COVERAGE DETERMINA-
22 TIONS.—

23 (1) STUDY.—The Secretary shall enter into an ar-
24 rangement with the Institute of Medicine of the National
25 Academy of Sciences under which the Institute shall con-
26 duct a study on the capabilities and information available
27 for local coverage determinations (including the application
28 of local medical review policies) under the medicare pro-
29 gram under title XVIII of the Social Security Act. Such
30 study shall examine—

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

33 (B) the extent to which such determinations are
34 based on evidence, including medical and scientific evi-
35 dence;

36 (C) the advantages and disadvantages of local cov-
37 erage decisionmaking, including the flexibility it offers

1 for ensuring timely patient access to new medical tech-
2 nology for which data are still be collected;

3 (D) whether local coverage determinations are
4 made, in the absence of adequate data, in order to col-
5 lect such data in a manner that results in coverage of
6 experimental items or services; and

7 (E) the advantages and disadvantages of main-
8 taining local medicare contractor advisory committees
9 that can advise on local coverage decisions based on an
10 open, collaborative public process.

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

16 (f) METHODS FOR DETERMINING PAYMENT BASIS FOR
17 NEW LAB TESTS.—Section 1833(h) (42 U.S.C. 1395l(h)) is
18 amended by adding at the end the following:

19 “(8)(A) The Secretary shall establish by regulation proce-
20 dures for determining the basis for, and amount of, payment
21 under this subsection for any clinical diagnostic laboratory test
22 with respect to which a new or substantially revised HCPCS
23 code is assigned on or after January 1, 2003 (in this para-
24 graph referred to as ‘new tests’).

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

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

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

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

7 “(iv) taking into account the comments and rec-
8 ommendations (and accompanying data) received at such
9 meeting, develops and makes available to the public
10 (through an Internet site and other appropriate mecha-
11 nisms) a list of proposed determinations with respect to the
12 appropriate basis for establishing a payment amount under
13 this subsection for each such code, together with an expla-
14 nation of the reasons for each such determination, the data
15 on which the determinations are based, and a request for
16 public written comments on the proposed determination;
17 and

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

26 “(C) Under the procedures established pursuant to sub-
27 paragraph (A), the Secretary shall—

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

30 “(ii) make available to the public the data (other than
31 proprietary data) considered in making such determina-
32 tions.

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

36 “(E) For purposes of this paragraph:

1 “(i) The term ‘HCPCS’ refers to the Health Care Pro-
2 cedure Coding System.

3 “(ii) A code shall be considered to be ‘substantially re-
4 vised’ if there is a substantive change to the definition of
5 the test or procedure to which the code applies (such as a
6 new analyte or a new methodology for measuring an exist-
7 ing analyte-specific test).”.

8 **SEC. 13. MISCELLANEOUS PROVISIONS.**

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

11 (1) IN GENERAL.—The Secretary of Health and
12 Human Services shall not require a hospital (including a
13 critical access hospital) to ask questions (or obtain informa-
14 tion) relating to the application of section 1862(b) of the
15 Social Security Act (relating to medicare secondary payor
16 provisions) in the case of reference laboratory services de-
17 scribed in paragraph (2), if the Secretary does not impose
18 such requirement in the case of such services furnished by
19 an independent laboratory.

20 (2) REFERENCE LABORATORY SERVICES DE-
21 SCRIBED.—Reference laboratory services described in this
22 paragraph are clinical laboratory diagnostic tests (or the
23 interpretation of such tests, or both) furnished without a
24 face-to-face encounter between the beneficiary and the hos-
25 pital involved and in which the hospital submits a claim
26 only for such test or interpretation.

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

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

33 “(d) In the case of hospital services and physicians’ serv-
34 ices that—

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

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

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

11 (c) PROMPT SUBMISSION OF OVERDUE REPORTS ON PAY-
12 MENT AND UTILIZATION OF OUTPATIENT THERAPY SERV-
13 ICES.—The Secretary of Health and Human Services shall sub-
14 mit to Congress as expeditiously as practicable the reports re-
15 quired under section 4541(d)(2) of the Balanced Budget Act
16 of 1997 (relating to alternatives to a single annual dollar cap
17 on outpatient therapy) and under section 221(d) of the Medi-
18 care, Medicaid, and SCHIP Balanced Budget Refinement Act
19 of 1999 (relating to utilization patterns for outpatient therapy).

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

23 (1) IN GENERAL.—Section 1861(dd)(5) (42 U.S.C.
24 1395x(dd)(5)) is amended by adding at the end the fol-
25 lowing new subparagraph:

26 “(D) In extraordinary, exigent, or other non-routine cir-
27 cumstances, such as unanticipated periods of high patient
28 loads, staffing shortages due to illness or other events, or tem-
29 porary travel of a patient outside a hospice program’s service
30 area, a hospice program may enter into arrangements with an-
31 other hospice program for the provision by that other program
32 of services described in paragraph (2)(A)(ii)(I). The provisions
33 of paragraph (2)(A)(ii)(II) shall apply with respect to the serv-
34 ices provided under such arrangements.”.

35 (2) CONFORMING PAYMENT PROVISION.—Section
36 1814(i) (42 U.S.C. 1395f(i)) is amended by adding at the
37 end the following new paragraph:

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

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