

104TH CONGRESS
1ST SESSION

H. R. 2389

To combat fraud and abuse in the medicare program, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 21, 1995

Mr. THOMAS (for himself, Mr. BILIRAKIS, and Mr. BARTON of Texas) introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committees on Commerce and the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To combat fraud and abuse in the medicare program, and
for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; REFERENCES IN ACT; TABLE OF**
4 **CONTENTS.**

5 (a) SHORT TITLE.—This Act may be cited as the
6 “Safeguarding Medicare Integrity Act of 1995”.

7 (b) AMENDMENTS TO SOCIAL SECURITY ACT.—Ex-
8 cept as otherwise specifically provided, whenever in this
9 Act an amendment is expressed in terms of an amendment

1 to or repeal of a section or other provision, the reference
 2 shall be considered to be made to that section or other
 3 provision of the Social Security Act.

4 (c) TABLE OF CONTENTS.—The table of contents of
 5 this Act is as follows:

Sec. 1. Short title; references in act; table of contents.

TITLE I—PREVENTING FRAUD AND ABUSE

Sec. 101. Increasing awareness of fraud and abuse.

Sec. 102. Beneficiary incentive programs.

Sec. 103. Intermediate sanctions for medicare health maintenance organiza-
 tions.

Sec. 104. Voluntary disclosure program.

Sec. 105. Revisions to current sanctions.

Sec. 106. Consolidated funding for anti-fraud and abuse activities under Medi-
 care Integrity Program.

Sec. 107. Permitting carriers to carry out prior authorization for certain items
 of durable medical equipment.

Sec. 108. Establishment of Health Care Anti-Fraud Task Force.

Sec. 109. Study of adequacy of private quality assurance programs.

TITLE II—REGULATORY RELIEF

Sec. 201. Clarification of level of intent required for imposition of sanctions.

Sec. 202. Clarification of and additions to exceptions to anti-kickback penalties.

Sec. 203. Solicitation and publication of modifications to existing safe harbors
 and new safe harbors.

Sec. 204. Issuance of advisory opinions under title XI.

6 **TITLE I—PREVENTING FRAUD** 7 **AND ABUSE**

8 **SEC. 101. INCREASING AWARENESS OF FRAUD AND ABUSE.**

9 (a) BENEFICIARY OUTREACH EFFORTS.—The Sec-
 10 retary of Health and Human Services (acting through the
 11 Administrator of the Health Care Financing Administra-
 12 tion and the Inspector General of the Department of
 13 Health and Human Services) shall make ongoing efforts
 14 (through public service announcements, publications, and

1 other appropriate methods) to alert individuals entitled to
2 benefits under the medicare program of the existence of
3 fraud and abuse committed against the program and the
4 costs to the program of such fraud and abuse, and of the
5 existence of the toll-free telephone line operated by the
6 Secretary to receive information on fraud and abuse com-
7 mitted against the program.

8 (b) CLARIFICATION OF REQUIREMENT TO PROVIDE
9 EXPLANATION OF MEDICARE BENEFITS.—The Secretary
10 shall provide an explanation of benefits under the medi-
11 care program with respect to each item or service for
12 which payment may be made under the program which
13 is furnished to an individual, without regard to whether
14 or not a deductible or coinsurance may be imposed against
15 the individual with respect to the item or service.

16 (c) PROVIDER OUTREACH EFFORTS; PUBLICATION
17 OF FRAUD ALERTS.—

18 (1) SPECIAL FRAUD ALERTS.—

19 (A) IN GENERAL.—

20 (i) REQUEST FOR SPECIAL FRAUD
21 ALERTS.—Any person may present, at any
22 time, a request to the Secretary to issue
23 and publish a special fraud alert.

24 (ii) SPECIAL FRAUD ALERT DE-
25 FINED.—In this section, a “special fraud

1 alert” is a notice which informs the public
2 of practices which the Secretary considers
3 to be suspect or of particular concern
4 under the medicare program or a State
5 health care program (as defined in section
6 1128(h) of the Social Security Act).

7 (B) ISSUANCE AND PUBLICATION OF SPE-
8 CIAL FRAUD ALERTS.—

9 (i) INVESTIGATION.—Upon receipt of
10 a request for a special fraud alert under
11 subparagraph (A), the Secretary shall in-
12 vestigate the subject matter of the request
13 to determine whether a special fraud alert
14 should be issued. If appropriate, the Sec-
15 retary (in consultation with the Attorney
16 General) shall issue a special fraud alert in
17 response to the request. All special fraud
18 alerts issued pursuant to this subpara-
19 graph shall be published in the Federal
20 Register.

21 (ii) CRITERIA FOR ISSUANCE.—In de-
22 termining whether to issue a special fraud
23 alert upon a request under subparagraph
24 (A), the Secretary may consider—

1 (I) whether and to what extent
2 the practices that would be identified
3 in the special fraud alert may result
4 in any of the consequences described
5 in section 203(b); and

6 (II) the extent and frequency of
7 the conduct that would be identified
8 in the special fraud alert.

9 (2) PUBLICATION OF ALL HCFA FRAUD ALERTS
10 IN FEDERAL REGISTER.—Each notice issued by the
11 Health Care Financing Administration which in-
12 forms the public of practices which the Secretary
13 considers to be suspect or of particular concern
14 under the medicare program or a State health care
15 program (as defined in section 1128(h) of the Social
16 Security Act) shall be published in the Federal Reg-
17 ister, without regard to whether or not the notice is
18 issued by a regional office of the Health Care Fi-
19 nancing Administration.

20 **SEC. 102. BENEFICIARY INCENTIVE PROGRAMS.**

21 (a) PROGRAM TO COLLECT INFORMATION ON FRAUD
22 AND ABUSE.—

23 (1) ESTABLISHMENT OF PROGRAM.—Not later
24 than 3 months after the date of the enactment of
25 this Act, the Secretary shall establish a program

1 under which the Secretary shall encourage individ-
2 uals to report to the Secretary information on indi-
3 viduals and entities who are engaging or who have
4 engaged in acts or omissions which constitute
5 grounds for the imposition of a sanction under sec-
6 tion 1128, section 1128A, or section 1128B of the
7 Social Security Act, or who have otherwise engaged
8 in fraud and abuse against the medicare program.

9 (2) PAYMENT OF PORTION OF AMOUNTS COL-
10 LECTED.—If an individual reports information to
11 the Secretary under the program established under
12 paragraph (1) which serves as the basis for the col-
13 lection by the Secretary or the Attorney General of
14 any amount of at least \$100 (other than any
15 amount paid as a penalty under section 1128B of
16 the Social Security Act), the Secretary may pay a
17 portion of the amount collected to the individual
18 (under procedures similar to those applicable under
19 section 7623 of the Internal Revenue Code of 1986
20 to payments to individuals providing information on
21 violations of such Code).

22 (b) PROGRAM TO COLLECT INFORMATION ON PRO-
23 GRAM EFFICIENCY.—

24 (1) ESTABLISHMENT OF PROGRAM.—Not later
25 than 3 months after the date of the enactment of

1 this Act, the Secretary shall establish a program
2 under which the Secretary shall encourage individ-
3 uals to submit to the Secretary suggestions on meth-
4 ods to improve the efficiency of the medicare pro-
5 gram.

6 (2) PAYMENT OF PORTION OF PROGRAM SAV-
7 INGS.—If an individual submits a suggestion to the
8 Secretary under the program established under
9 paragraph (1) which is adopted by the Secretary and
10 which results in savings to the program, the Sec-
11 retary may make a payment to the individual of
12 such amount as the Secretary considers appropriate.

13 **SEC. 103. INTERMEDIATE SANCTIONS FOR MEDICARE**
14 **HEALTH MAINTENANCE ORGANIZATIONS.**

15 (a) APPLICATION OF INTERMEDIATE SANCTIONS FOR
16 ANY PROGRAM VIOLATIONS.—

17 (1) IN GENERAL.—Section 1876(i)(1) (42
18 U.S.C. 1395mm(i)(1)) is amended by striking “the
19 Secretary may terminate” and all that follows and
20 inserting the following: “in accordance with proce-
21 dures established under paragraph (9), the Secretary
22 may at any time terminate any such contract or may
23 impose the intermediate sanctions described in para-
24 graph (6)(B) or (6)(C) (whichever is applicable) on

1 the eligible organization if the Secretary determines
2 that the organization—

3 “(A) has failed substantially to carry out the
4 contract;

5 “(B) is carrying out the contract in a manner
6 inconsistent with the efficient and effective adminis-
7 tration of this section;

8 “(C) is operating in a manner that is not in the
9 best interests of the individuals covered under the
10 contract; or

11 “(D) no longer substantially meets the applica-
12 ble conditions of subsections (b), (c), (e), and (f).”.

13 (2) OTHER INTERMEDIATE SANCTIONS FOR
14 MISCELLANEOUS PROGRAM VIOLATIONS.—Section
15 1876(i)(6) (42 U.S.C. 1395mm(i)(6)) is amended by
16 adding at the end the following new subparagraph:

17 “(C) In the case of an eligible organization for which
18 the Secretary makes a determination under paragraph (1)
19 the basis of which is not described in subparagraph (A),
20 the Secretary may apply the following intermediate sanc-
21 tions:

22 “(i) Civil money penalties of not more than
23 \$25,000 for each determination under paragraph (1)
24 if the deficiency that is the basis of the determina-
25 tion has directly adversely affected (or has the sub-

1 stantial likelihood of adversely affecting) an individ-
2 ual covered under the organization’s contract.

3 “(ii) Civil money penalties of not more than
4 \$10,000 for each week beginning after the initiation
5 of procedures by the Secretary under paragraph (9)
6 during which the deficiency that is the basis of a de-
7 termination under paragraph (1) exists.

8 “(iii) Suspension of enrollment of individuals
9 under this section after the date the Secretary noti-
10 fies the organization of a determination under para-
11 graph (1) and until the Secretary is satisfied that
12 the deficiency that is the basis for the determination
13 has been corrected and is not likely to recur.”.

14 (3) PROCEDURES FOR IMPOSING SANCTIONS.—

15 Section 1876(i) (42 U.S.C. 1395mm(i)) is amended
16 by adding at the end the following new paragraph:

17 “(9) The Secretary may terminate a contract with an
18 eligible organization under this section or may impose the
19 intermediate sanctions described in paragraph (6) on the
20 organization in accordance with formal investigation and
21 compliance procedures established by the Secretary under
22 which—

23 “(A) the Secretary provides the organization
24 with the opportunity to develop and implement a
25 corrective action plan to correct the deficiencies that

1 were the basis of the Secretary's determination
2 under paragraph (1);

3 “(B) the Secretary shall impose more severe
4 sanctions on organizations that have a history of de-
5 ficiencies or that have not taken steps to correct de-
6 ficiencies the Secretary has brought to their atten-
7 tion;

8 “(C) there are no unreasonable or unnecessary
9 delays between the finding of a deficiency and the
10 imposition of sanctions; and

11 “(D) the Secretary provides the organization
12 with reasonable notice and opportunity for hearing
13 (including the right to appeal an initial decision) be-
14 fore imposing any sanction or terminating the con-
15 tract.”.

16 (4) CONFORMING AMENDMENTS.—(A) Section
17 1876(i)(6)(B) (42 U.S.C. 1395mm(i)(6)(B)) is
18 amended by striking the second sentence.

19 (B) Section 1876(i)(6) (42 U.S.C.
20 1395mm(i)(6)) is further amended by adding at the
21 end the following new subparagraph:

22 “(D) The provisions of section 1128A (other than
23 subsections (a) and (b)) shall apply to a civil money pen-
24 alty under subparagraph (A) or (B) in the same manner

1 as they apply to a civil money penalty or proceeding under
2 section 1128A(a).”.

3 (b) EFFECTIVE DATE.—The amendments made by
4 this section shall apply with respect to contract years be-
5 ginning on or after January 1, 1996.

6 **SEC. 104. VOLUNTARY DISCLOSURE PROGRAM.**

7 Title XI (42 U.S.C. 1301 et seq.) is amended by in-
8 serting after section 1128B the following new section:

9 “VOLUNTARY DISCLOSURE OF ACTS OR OMISSIONS
10 “SEC. 1129. (a) ESTABLISHMENT OF VOLUNTARY
11 DISCLOSURE PROGRAM.—Not later than 3 months after
12 the date of the enactment of the Omnibus Budget Rec-
13 onciliation Act of 1995, the Secretary shall establish a
14 program to encourage individuals and entities to volun-
15 tarily disclose to the Secretary information on acts or
16 omissions of the individual or entity which constitute
17 grounds for the imposition of a sanction described in sec-
18 tion 1128, 1128A, or 1128B.

19 “(b) EFFECT OF VOLUNTARY DISCLOSURE.—If an
20 individual or entity voluntarily discloses information with
21 respect to an act or omission to the Secretary under sub-
22 section (a), the following rules shall apply:

23 “(1) The Secretary may waive, reduce, or other-
24 wise mitigate any sanction which would otherwise be
25 applicable to the individual or entity under section

1 1128, 1128A, or 1128B as a result of the act or
2 omission involved.

3 “(2) No qui tam action may be brought pursu-
4 ant to chapter 37 of title 31, United States Code,
5 against the individual or entity with respect to the
6 act or omission involved.”.

7 **SEC. 105. REVISIONS TO CURRENT SANCTIONS.**

8 (a) INCREASE IN AMOUNT OF CRIMINAL FINES.—
9 Section 1128B (42 U.S.C. 1320a–7b) is amended by strik-
10 ing “\$25,000” each place it appears in subsections (a),
11 (b)(1), (b)(2), (c), and (d) and inserting “\$250,000”.

12 (b) ESTABLISHMENT OF MINIMUM PERIOD OF EX-
13 CLUSION FOR CERTAIN INDIVIDUALS AND ENTITIES SUB-
14 JECT TO PERMISSIVE EXCLUSION.—Section 1128(c)(3)
15 (42 U.S.C. 1320a–7(c)(3)) is amended by adding at the
16 end the following new subparagraphs:

17 “(D) In the case of an exclusion of an individual or
18 entity under paragraph (1), (2), or (3) of subsection (b),
19 the period of the exclusion shall be 3 years, unless the
20 Secretary determines in accordance with published regula-
21 tions that a shorter period is appropriate because of miti-
22 gating circumstances or that a longer period is appro-
23 priate because of aggravating circumstances.

24 “(E) In the case of an exclusion of an individual or
25 entity under subsection (b)(4) or (b)(5), the period of the

1 exclusion shall not be less than the period during which
2 the individual's or entity's license to provide health care
3 is revoked, suspended, or surrendered, or the individual
4 or the entity is excluded or suspended from a Federal or
5 State health care program.

6 “(F) In the case of an exclusion of an individual or
7 entity under subsection (b)(6)(B), the period of the exclu-
8 sion shall be not less than 1 year.”.

9 (c) EFFECTIVE DATE.—The amendments made by
10 this section shall apply with respect to acts or omissions
11 occurring on or after January 1, 1996.

12 **SEC. 106. CONSOLIDATED FUNDING FOR ANTI-FRAUD AND**
13 **ABUSE ACTIVITIES UNDER MEDICARE INTEG-**
14 **RITY PROGRAM.**

15 (a) ESTABLISHMENT OF MEDICARE INTEGRITY PRO-
16 GRAM.—Title XVIII is amended by adding at the end the
17 following new section:

18 “MEDICARE INTEGRITY PROGRAM

19 “SEC. 1894. (a) ESTABLISHMENT OF PROGRAM.—
20 There is hereby established the Medicare Integrity Pro-
21 gram (hereafter in this section referred to as the ‘Pro-
22 gram’) under which the Secretary shall promote the integ-
23 rity of the medicare program by entering into contracts
24 in accordance with this section with eligible private entities
25 to carry out the activities described in subsection (b).

1 “(b) ACTIVITIES DESCRIBED.—The activities de-
2 scribed in this subsection are as follows:

3 “(1) Review of activities of providers of services
4 or other individuals and entities furnishing items
5 and services for which payment may be made under
6 this title (including skilled nursing facilities and
7 home health agencies), including medical and utiliza-
8 tion review and fraud review (employing similar
9 standards, processes, and technologies used by pri-
10 vate health plans, including equipment and software
11 technologies which surpass the capability of the
12 equipment and technologies used in the review of
13 claims under this title as of the date of the enact-
14 ment of the Omnibus Budget Reconciliation Act of
15 1995).

16 “(2) Audit of cost reports.

17 “(3) Determinations as to whether payment
18 should not be, or should not have been, made under
19 this title by reason of section 1862(b), and recovery
20 of payments that should not have been made.

21 “(4) Education of providers of services, bene-
22 ficiaries, and other persons with respect to payment
23 integrity and benefit quality assurance issues.

1 “(c) ELIGIBILITY OF ENTITIES.—An entity is eligible
2 to enter into a contract under the Program to carry out
3 any of the activities described in subsection (b) if—

4 “(1) the entity has demonstrated capability to
5 carry out such activities;

6 “(2) in carrying out such activities, the entity
7 agrees to cooperate with the Inspector General of
8 the Department of Health and Human Services, the
9 Attorney General of the United States, and other
10 law enforcement agencies, as appropriate, in the in-
11 vestigation and deterrence of fraud and abuse in re-
12 lation to this title and in other cases arising out of
13 such activities;

14 “(3) the entity’s financial holdings, interests, or
15 relationships will not interfere with its ability to per-
16 form the functions to be required by the contract in
17 an effective and impartial manner; and

18 “(4) the entity meets such other requirements
19 as the Secretary may impose.

20 “(d) PROCESS FOR ENTERING INTO CONTRACTS.—
21 The Secretary shall enter into contracts under the Pro-
22 gram in accordance with such procedures as the Secretary
23 may by regulation establish, except that such procedures
24 shall include the following:

1 “(1) The Secretary shall determine the appro-
2 priate number of separate contracts which are nec-
3 essary to carry out the Program and the appropriate
4 times at which the Secretary shall enter into such
5 contracts, except that contracts must be in effect to
6 carry out the activities described in subsection (b)
7 with respect to services, providers, and investigations
8 and other activities for all fiscal years beginning on
9 or after October 1, 1998.

10 “(2) The provisions of section 1153(e)(1) shall
11 apply to contracts and contracting authority under
12 this section, except that competitive procedures must
13 be used when entering into new contracts under this
14 section, or at any other time considered appropriate
15 by the Secretary.

16 “(3) A contract under this section may be re-
17 newed without regard to any provision of law requir-
18 ing competition if the contractor has met or ex-
19 ceeded the performance requirements established in
20 the current contract.

21 “(e) LIMITATION ON CONTRACTOR LIABILITY.—The
22 Secretary shall by regulation provide for the limitation of
23 a contractor’s liability for actions taken to carry out a con-
24 tract under the Program, and such regulation shall, to the
25 extent the Secretary finds appropriate, employ the same

1 or comparable standards and other substantive and proce-
2 dural provisions as are contained in section 1157.

3 “(f) TRANSFER OF AMOUNTS TO MEDICARE ANTI-
4 FRAUD AND ABUSE TRUST FUND.—For each fiscal year,
5 the Secretary shall transfer from the Federal Hospital In-
6 surance Trust Fund and the Federal Supplementary Med-
7 ical Insurance Trust Fund to the Medicare Anti-Fraud
8 and Abuse Trust Fund under subsection (g) an amount
9 equal to the total amount of expenditures which would
10 have been made by the Secretary under this title (whether
11 through contracts with fiscal intermediaries under section
12 1816, contracts with carriers under section 1842, or other-
13 wise) during the year to carry out the activities described
14 in subsection (b) if the Program had not been in effect
15 (as estimated by the Secretary prior to the beginning of
16 the year). Such transfer shall be in an allocation as rea-
17 sonably reflects the proportion of such expenditures asso-
18 ciated with part A and part B.

19 “(g) MEDICARE ANTI-FRAUD AND ABUSE TRUST
20 FUND.—

21 “(1) ESTABLISHMENT.—

22 “(A) IN GENERAL.—There is hereby estab-
23 lished in the Treasury of the United States the
24 Anti-Fraud and Abuse Trust Fund (hereafter
25 in this subsection referred to as the ‘Trust

1 Fund'). The Trust Fund shall consist of such
2 gifts and bequests as may be made as provided
3 in subparagraph (B) and such amounts as may
4 be deposited in the Trust Fund as provided in
5 subsection (f), paragraph (3), and title XI.

6 “(B) AUTHORIZATION TO ACCEPT GIFTS
7 AND BEQUESTS.—The Trust Fund is author-
8 ized to accept on behalf of the United States
9 money gifts and bequests made unconditionally
10 to the Trust Fund, for the benefit of the Trust
11 Fund or any activity financed through the
12 Trust Fund.

13 “(2) INVESTMENT.—

14 “(A) IN GENERAL.—The Secretary of the
15 Treasury shall invest such amounts of the Fund
16 as such Secretary determines are not required
17 to meet current withdrawals from the Fund.
18 Such investments may be made only in interest-
19 bearing obligations of the United States. For
20 such purpose, such obligations may be acquired
21 on original issue at the issue price, or by pur-
22 chase of outstanding obligations at the market
23 price.

1 “(B) SALE OF OBLIGATIONS.—Any obliga-
2 tion acquired by the Fund may be sold by the
3 Secretary of the Treasury at the market price.

4 “(C) AVAILABILITY OF INCOME.—Any in-
5 terest derived from obligations acquired by the
6 Fund, and proceeds from any sale or redemp-
7 tion of such obligations, are hereby appro-
8 priated to the Fund.

9 “(3) AMOUNTS DEPOSITED INTO TRUST
10 FUND.—There shall be deposited in the Trust
11 Fund—

12 “(A) that portion of amounts recovered in
13 relation to section 1128A arising out of a claim
14 under title XVIII as remains after application
15 of subsection (f)(2) (relating to repayment of
16 the Federal Hospital Insurance Trust Fund or
17 the Federal Supplementary Medical Insurance
18 Trust Fund) of that section, as may be applica-
19 ble,

20 “(B) fines imposed under section 1128B
21 arising out of a claim under this title, and

22 “(C) penalties and damages imposed (other
23 than funds awarded to a relator or for restitu-
24 tion) under sections 3729 through 3732 of title
25 31, United States Code (pertaining to false

1 claims) in cases involving claims relating to pro-
2 grams under title XVIII or XIX.

3 “(4) DIRECT APPROPRIATION OF FUNDS TO
4 CARRY OUT PROGRAM.—There are appropriated
5 from the Trust Fund for each fiscal year such
6 amounts as are necessary to carry out the Medicare
7 Integrity Program under this section.

8 “(5) ANNUAL REPORT.—The Secretary shall
9 submit an annual report to Congress on the amount
10 of revenue which is generated and disbursed by the
11 Trust Fund in each fiscal year.”.

12 (b) ELIMINATION OF FI AND CARRIER RESPONSIBIL-
13 ITY FOR CARRYING OUT ACTIVITIES SUBJECT TO PRO-
14 GRAM.—

15 (1) RESPONSIBILITIES OF FISCAL
16 INTERMEDIARIES UNDER PART A.—Section 1816
17 (42 U.S.C. 1395h) is amended by adding at the end
18 the following new subsection:

19 “(1) No agency or organization may carry out (or re-
20 ceive payment for carrying out) any activity pursuant to
21 an agreement under this section to the extent that the ac-
22 tivity is carried out pursuant to a contract under the Med-
23 icare Integrity Program under section 1894.”.

24 (2) RESPONSIBILITIES OF CARRIERS UNDER
25 PART B.—Section 1842(c) (42 U.S.C. 1395u(c)) is

1 amended by adding at the end the following new
2 paragraph:

3 “(6) No carrier may carry out (or receive payment
4 for carrying out) any activity pursuant to a contract under
5 this subsection to the extent that the activity is carried
6 out pursuant to a contract under the Medicare Integrity
7 Program under section 1894.”.

8 (c) CONFORMING AMENDMENT.—Section
9 1128A(f)(3) (42 U.S.C. 1320a-7a(f)(3)) is amended by
10 striking “as miscellaneous receipts of the Treasury of the
11 United States” and inserting “in the Anti-Fraud and
12 Abuse Trust Fund established under section 1145”.

13 **SEC. 107. PERMITTING CARRIERS TO CARRY OUT PRIOR**
14 **AUTHORIZATION FOR CERTAIN ITEMS OF DU-**
15 **RABLE MEDICAL EQUIPMENT.**

16 (a) IN GENERAL.—Section 1834(a)(15) (42 U.S.C.
17 1395m(a)(15)), as amended by section 135(b) of the So-
18 cial Security Act Amendments of 1994, is amended by
19 adding at the end the following new subparagraphs:

20 “(D) APPLICATION BY CARRIERS.—A car-
21 rier may develop (and periodically update) a list
22 of items under subparagraph (A) and a list of
23 suppliers under subparagraph (B) in the same
24 manner as the Secretary may develop (and peri-
25 odically update) such lists.

1 fraud offenses. Nothing in this section may be construed
2 as affecting the powers of the Attorney General or any
3 other individual.

4 (b) OPERATIONS OF TASK FORCE.—The Attorney
5 General shall establish and operate the Task Force in a
6 manner such that—

7 (1) at least one fully staffed operational seg-
8 ment of the Task Force (including at least one Fed-
9 eral representative engaged in Task Force activities
10 on a full-time basis) shall operate in each judicial
11 district of the United States; and

12 (2) the Task Force maintains separate account-
13 ing of its finances, personnel, case load, and resolu-
14 tion of claims and actions.

15 (c) ADVISORY GROUP DESCRIBED.—The Advisory
16 Group described in this subsection is a group consisting
17 of the following individuals (or their designees):

18 (1) The Secretary of Health and Human Serv-
19 ices.

20 (2) The Secretary of the Treasury.

21 (3) The Secretary of Veterans' Affairs.

22 (4) The Chair of the Board of Governors of the
23 United States Postal Service.

1 **SEC. 109. STUDY OF ADEQUACY OF PRIVATE QUALITY AS-**
2 **SURANCE PROGRAMS.**

3 (a) IN GENERAL.—The Administrator of the Health
4 Care Financing Administration (acting through the Direc-
5 tor of the Office of Research and Development) shall enter
6 into an agreement with a private entity to conduct a study
7 during the 5-year period beginning on the date of the en-
8 actment of this Act of the adequacy of the quality assur-
9 ance programs and consumer protections used by eligible
10 organizations with risk-sharing contracts under section
11 1876 of the Social Security Act, and shall include in the
12 study an analysis of the effectiveness of such organizations
13 in protecting enrollees against the risk of insufficient pro-
14 vision of benefits which may result from utilization con-
15 trols.

16 (b) REPORT.—Not later than 6 months after the con-
17 clusion of the 5-year period described in subsection (a),
18 the Administrator shall submit a report to Congress on
19 the study conducted under such subsection.

20 **TITLE II—REGULATORY RELIEF**

21 **SEC. 201. CLARIFICATION OF LEVEL OF INTENT REQUIRED**
22 **FOR IMPOSITION OF SANCTIONS.**

23 (a) CLARIFICATION OF LEVEL OF KNOWLEDGE RE-
24 QUIRED FOR IMPOSITION OF CIVIL MONETARY PEN-
25 ALTIES.—

1 (1) IN GENERAL.—Section 1128A(a) (42
2 U.S.C. 1320a–7a(a)) is amended—

3 (A) in paragraphs (1) and (2), by inserting
4 “knowingly” before “presents” each place it ap-
5 pears; and

6 (B) in paragraph (3), by striking “gives”
7 and inserting “knowingly gives or causes to be
8 given”.

9 (2) DEFINITION OF STANDARD.—Section
10 1128A(i) (42 U.S.C. 1320a–7a(i)) is amended by
11 adding at the end the following new paragraph:

12 “(6) The term ‘should know’ means that a per-
13 son, with respect to information—

14 “(A) acts in deliberate ignorance of the
15 truth or falsity of the information; or

16 “(B) acts in reckless disregard of the truth
17 or falsity of the information,

18 and no proof of specific intent to defraud is re-
19 quired.”.

20 (b) CLARIFICATION OF EFFECT AND APPLICATION
21 OF SAFE HARBOR EXCEPTIONS.—For purposes of section
22 1128B(b)(3) of the Social Security Act, the specification
23 of any payment practice in regulations promulgated pur-
24 suant to section 14(a) of the Medicare and Medicaid Pro-
25 gram Patient Protection Act of 1987 is—

1 (1) solely for the purpose of adding additional
2 exceptions to the types of conduct which are not
3 subject to an anti-kickback penalty under such sec-
4 tion and not for the purpose of limiting the scope of
5 such exceptions; and

6 (2) for the purpose of prescribing criteria for
7 qualifying for such an exception notwithstanding the
8 intent of the party involved.

9 (c) **LIMITING IMPOSITION OF ANTI-KICKBACK PEN-**
10 **ALTIES TO ACTIONS WITH SIGNIFICANT PURPOSE TO IN-**
11 **DUCE REFERRALS.**—Section 1128B(b)(2) (42 U.S.C.
12 1320a–7b(b)(2)) is amended in the matter preceding sub-
13 paragraph (A) by striking “to induce” and inserting “for
14 the significant purpose of inducing”.

15 (d) **EFFECTIVE DATE.**—The amendments made by
16 this section shall apply to acts or omissions occurring on
17 or after January 1, 1996.

18 **SEC. 202. CLARIFICATION OF AND ADDITIONS TO EXCEP-**
19 **TIONS TO ANTI-KICKBACK PENALTIES.**

20 (a) **DISCOUNTS, RISK-SHARING AND OTHER MAN-**
21 **AGED CARE ARRANGEMENTS, AND DE MINIMIS REMU-**
22 **NERATION.**—Section 1128B(b)(3) (42 U.S.C. 1320a–
23 7b(b)(3)) is amended—

24 (1) by striking “and” at the end of subpara-
25 graph (D);

1 (2) by striking the period at the end of sub-
2 paragraph (E) and inserting “; and”; and

3 (3) by adding at the end the following new sub-
4 paragraph:

5 “(F) any reduction in cost sharing or increased
6 benefits given to an individual, any amounts paid to
7 a provider for an item or service furnished to an in-
8 dividual, any discount or reduction in price given by
9 the provider for such an item or service, or any
10 other remuneration if—

11 “(i) the item or service is provided—

12 “(I) the item or service is provided
13 through an organization described in sec-
14 tion 1877(b)(3), or is provided through
15 such an organization on behalf of another
16 entity (including but not limited to a self-
17 insured employer or indemnity plan) that
18 assumes financial risk for the provision of
19 the item or service, or

20 “(II) the item or service is provided
21 through any capitation, risk-sharing, or
22 disease management program (or any pro-
23 gram found by the Secretary to be similar
24 to such a program) and the Secretary and
25 the directors of State health care programs

1 a notice in the Federal Register soliciting proposals,
2 which will be accepted during a 60-day period, for—

3 (A) modifications to existing safe harbors
4 issued pursuant to section 14(a) of the Medi-
5 care and Medicaid Patient and Program Protec-
6 tion Act of 1987;

7 (B) additional safe harbors specifying pay-
8 ment practices that shall not be treated as a
9 criminal offense under section 1128B(b) of the
10 Social Security Act and shall not serve as the
11 basis for an exclusion under section 1128(b)(7)
12 of such Act; and

13 (C) special fraud alerts to be issued pursu-
14 ant to section 101(c).

15 (2) PUBLICATION OF PROPOSED MODIFICA-
16 TIONS AND PROPOSED ADDITIONAL SAFE HAR-
17 BORS.—Not later than 120 days after receiving the
18 proposals described in subparagraphs (A) and (B) of
19 paragraph (1), the Secretary, after considering such
20 proposals in consultation with the Attorney General,
21 shall publish in the Federal Register proposed modi-
22 fications to existing safe harbors and proposed addi-
23 tional safe harbors, if appropriate, with a 60-day
24 comment period. After considering any public com-
25 ments received during this period, the Secretary

1 shall issue final rules modifying the existing safe
2 harbors and establishing new safe harbors, as appro-
3 priate.

4 (3) REPORT.—The Inspector General shall, in
5 an annual report to Congress or as part of the year-
6 end semiannual report required by section 5 of the
7 Inspector General Act of 1978, describe the propos-
8 als received under subparagraphs (A) and (B) of
9 paragraph (1) and explain which proposals were in-
10 cluded in the publication described in paragraph (2),
11 which proposals were not included in that publica-
12 tion, and the reasons for the rejection of the propos-
13 als that were not included.

14 (b) CRITERIA FOR MODIFYING AND ESTABLISHING
15 SAFE HARBORS.—In modifying and establishing safe har-
16 bors under subsection (a)(2), the Secretary may consider
17 the extent to which providing a safe harbor for the speci-
18 fied payment practice may result in any of the following:

19 (1) An increase or decrease in access to health
20 care services.

21 (2) An increase or decrease in the quality of
22 health care services.

23 (3) An increase or decrease in patient freedom
24 of choice among health care providers.

1 (4) An increase or decrease in competition
2 among health care providers.

3 (5) An increase or decrease in the cost to health
4 care programs of the Federal Government.

5 (6) An increase or decrease in the potential
6 overutilization of health care services.

7 (7) Any other factors the Secretary deems ap-
8 propriate in the interest of preventing fraud and
9 abuse in health care programs of the Federal Gov-
10 ernment.

11 **SEC. 204. ISSUANCE OF ADVISORY OPINIONS UNDER TITLE**

12 **XI.**

13 (a) IN GENERAL.—Title XI (42 U.S.C. 1301 et seq.),
14 as amended by section 104(a), is amended by inserting
15 after section 1129 the following new section:

16 “ADVISORY OPINIONS

17 “SEC. 1130. (a) ISSUANCE OF ADVISORY OPIN-
18 IONS.—The Secretary shall issue written advisory opinions
19 as provided in this section.

20 “(b) MATTERS SUBJECT TO ADVISORY OPINIONS.—
21 The Secretary shall issue advisory opinions as to the fol-
22 lowing matters:

23 “(1) What constitutes prohibited remuneration
24 within the meaning of section 1128B(b).

25 “(2) Whether an arrangement or proposed ar-
26 rangement satisfies the criteria set forth in section

1 1128B(b)(3) for activities which do not result in
2 prohibited remuneration.

3 “(3) Whether an arrangement or proposed ar-
4 rangement satisfies the criteria which the Secretary
5 has established, or shall establish by regulation for
6 activities which do not result in prohibited remu-
7 neration.

8 “(4) What constitutes an inducement to reduce
9 or limit services to individuals entitled to benefits
10 under title XVIII or title XIX within the meaning
11 of section 1128B(b).

12 “(5) Whether any activity or proposed activity
13 constitutes grounds for the imposition of a sanction
14 under section 1128, 1128A, or 1128B.

15 “(c) MATTERS NOT SUBJECT TO ADVISORY OPIN-
16 IONS.—Such advisory opinions shall not address the fol-
17 lowing matters:

18 “(1) Whether the fair market value shall be, or
19 was paid or received for any goods, services or prop-
20 erty.

21 “(2) Whether an individual is a bona fide em-
22 ployee within the requirements of section 3121(d)(2)
23 of the Internal Revenue Code of 1986.

24 “(d) EFFECT OF ADVISORY OPINIONS.—

1 “(1) BINDING AS TO SECRETARY AND PARTIES
2 INVOLVED.—Each advisory opinion issued by the
3 Secretary shall be binding as to the Secretary and
4 the party or parties requesting the opinion.

5 “(2) FAILURE TO SEEK OPINION.—The failure
6 of a party to seek an advisory opinion may not be
7 introduced into evidence to prove that the party in-
8 tended to violate the provisions of sections 1128,
9 1128A, or 1128B.

10 “(e) REGULATIONS.—

11 “(1) IN GENERAL.—Not later than 180 days
12 after the date of the enactment of this section, the
13 Secretary shall issue regulations to carry out this
14 section. Such regulations shall provide for—

15 “(A) the procedure to be followed by a
16 party applying for an advisory opinion;

17 “(B) the procedure to be followed by the
18 Secretary in responding to a request for an ad-
19 visory opinion;

20 “(C) the interval in which the Secretary
21 shall respond;

22 “(D) the reasonable fee to be charged to
23 the party requesting an advisory opinion; and

24 “(E) the manner in which advisory opin-
25 ions will be made available to the public.

1 “(2) SPECIFIC CONTENTS.—Under the regula-
2 tions promulgated pursuant to paragraph (1)—

3 “(A) the Secretary shall be required to re-
4 spond to a party requesting an advisory opinion
5 by not later than 30 days after the request is
6 made; and

7 “(B) the fee charged to the party request-
8 ing an advisory opinion shall be equal to the
9 costs incurred by the Secretary in responding to
10 the request.”.

11 (b) EFFECTIVE DATE.—The amendment made by
12 subsection (a) shall apply to requests for advisory opinions
13 made on or after January 1, 1996.

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