

Calendar No. 578

103D CONGRESS
2D SESSION

S. 2381

A BILL

To require the Secretary of Health and Human Services to provide health care fraud and abuse guidance, and for other purposes.

AUGUST 18, 1994

Read the second time and placed on the calendar

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IN THE SENATE OF THE UNITED STATES

AUGUST 11, 1994

Mr. COHEN introduced the following bill; which was read the first time

AUGUST 18, 1994

Read the second time and placed on the calendar

A BILL

To require the Secretary of Health and Human Services to provide health care fraud and abuse guidance, 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. HEALTH CARE FRAUD AND ABUSE GUIDANCE.**

4 (a) SOLICITATION AND PUBLICATION OF MODIFICA-
5 TIONS TO EXISTING SAFE HARBORS AND NEW SAFE
6 HARBORS.—

7 (1) IN GENERAL.—

1 (A) SOLICITATION OF PROPOSALS FOR
2 SAFE HARBORS.—Not later than January 1,
3 1995, and not less than annually thereafter, the
4 Secretary of Health and Human Services (here-
5 after in this section referred to as the “Sec-
6 retary”) shall publish a notice in the Federal
7 Register soliciting proposals, which will be ac-
8 cepted during a 60-day period, for—

9 (i) modifications to existing safe har-
10 bors issued pursuant to section 14(a) of
11 the Medicare and Medicaid Patient and
12 Program Protection Act of 1987 (42
13 U.S.C. 1320a–7b note);

14 (ii) additional safe harbors specifying
15 payment practices that shall not be treated
16 as a criminal offense under section
17 1128B(b) of the Social Security Act the
18 (42 U.S.C. 1320a–7b(b)) and shall not
19 serve as the basis for an exclusion under
20 section 1128(b)(7) of such Act (42 U.S.C.
21 1320a–7(b)(7));

22 (iii) interpretive rulings to be issued
23 pursuant to subsection (b); and

24 (iv) special fraud alerts to be issued
25 pursuant to subsection (c).

1 (B) PUBLICATION OF PROPOSED MODI-
2 FICATIONS AND PROPOSED ADDITIONAL STATE
3 HARBORS.—After considering the proposals de-
4 scribed in clauses (i) and (ii) of subparagraph
5 (A), the Secretary, in consultation with the At-
6 torney General, shall publish in the Federal
7 Register proposed modifications to existing safe
8 harbors and proposed additional safe harbors, if
9 appropriate, with a 60-day comment period.
10 After considering any public comments received
11 during this period, the Secretary shall issue
12 final rules modifying the existing safe harbors
13 and establishing new safe harbors, as appro-
14 priate.

15 (C) REPORT.—The Inspector General of
16 the Department of Health and Human Services
17 (hereafter in this section referred to as the “In-
18 spector General”) shall, in an annual report to
19 Congress or as part of the year-end semiannual
20 report required by section 5 of the Inspector
21 General Act of 1978 (5 U.S.C. App.), describe
22 the proposals received under clauses (i) and (ii)
23 of subparagraph (A) and explain which propos-
24 als were included in the publication described in
25 subparagraph (B), which proposals were not in-

1 cluded in that publication, and the reasons for
2 the rejection of the proposals that were not in-
3 cluded.

4 (2) CRITERIA FOR MODIFYING AND ESTABLISH-
5 ING SAFE HARBORS.—In modifying and establishing
6 safe harbors under paragraph (1)(B), the Secretary
7 may consider the extent to which providing a safe
8 harbor for the specified payment practice may result
9 in any of the following:

10 (A) An increase or decrease in access to
11 health care services.

12 (B) An increase or decrease in the quality
13 of health care services.

14 (C) An increase or decrease in patient free-
15 dom of choice among health care providers.

16 (D) An increase or decrease in competition
17 among health care providers.

18 (E) An increase or decrease in the ability
19 of health care facilities to provide services in
20 medically underserved areas or to medically un-
21 derserved populations.

22 (F) An increase or decrease in the cost to
23 Government health care programs.

24 (G) An increase or decrease in the poten-
25 tial overutilization of health care services.

1 (H) The existence or nonexistence of any
2 potential financial benefit to a health care pro-
3 fessional or provider which may vary based on
4 their decisions of—

5 (i) whether to order a health care
6 item or service; or

7 (ii) whether to arrange for a referral
8 of health care items or services to a par-
9 ticular practitioner or provider.

10 (I) Any other factors the Secretary deems
11 appropriate in the interest of preventing fraud
12 and abuse in Government health care programs.

13 (b) INTERPRETIVE RULINGS.—

14 (1) IN GENERAL.—

15 (A) REQUEST FOR INTERPRETIVE RUL-
16 ING.—Any person may present, at any time, a
17 request to the Inspector General for a state-
18 ment of the Inspector General’s current inter-
19 pretation of the meaning of a specific aspect of
20 the application of sections 1128A and 1128B of
21 the Social Security Act (hereafter in this sec-
22 tion referred to as an “interpretive ruling”).

23 (B) ISSUANCE AND EFFECT OF INTERPRE-
24 TIVE RULING.—

1 (i) IN GENERAL.—If appropriate, the
2 Inspector General shall in consultation
3 with the Attorney General, issue an inter-
4 pretive ruling in response to a request de-
5 scribed in subparagraph (A). Interpretive
6 rulings shall not have the force of law and
7 shall be treated as an interpretive rule
8 within the meaning of section 553(b) of
9 title 5, United States Code. All interpretive
10 rulings issued pursuant to this provision
11 shall be published in the Federal Register
12 or otherwise made available for public in-
13 spection.

14 (ii) REASONS FOR DENIAL.—If the In-
15 spector General does not issue an interpre-
16 tive ruling in response to a request de-
17 scribed in subparagraph (A), the Inspector
18 General shall notify the requesting party of
19 such decision and shall identify the reasons
20 for such decision.

21 (2) CRITERIA FOR INTERPRETIVE RULINGS.—

22 (A) IN GENERAL.—In determining whether
23 to issue an interpretive ruling under paragraph
24 (1)(B), the Inspector General may consider—

1 (i) whether and to what extent the re-
2 quest identifies an ambiguity within the
3 language of the statute, the existing safe
4 harbors, or previous interpretive rulings;
5 and

6 (ii) whether the subject of the re-
7 quested interpretive ruling can be ade-
8 quately addressed by interpretation of the
9 language of the statute, the existing safe
10 harbor rules, or previous interpretive rul-
11 ings, or whether the request would require
12 a substantive ruling not authorized under
13 this subsection.

14 (B) NO RULINGS ON FACTUAL ISSUES.—
15 The Inspector General shall not give an inter-
16 pretive ruling on any factual issue, including
17 the intent of the parties or the fair market
18 value of particular leased space or equipment.

19 (c) SPECIAL FRAUD ALERTS.—

20 (1) IN GENERAL.—

21 (A) REQUEST FOR SPECIAL FRAUD
22 ALERTS.—Any person may present, at any
23 time, a request to the Inspector General for a
24 notice which informs the public of practices
25 which the Inspector General considers to be

1 suspect or of particular concern under section
2 1128B(b) of the Social Security Act (42 U.S.C.
3 1320a–7b(b)) (hereafter in this subsection re-
4 ferred to as a “special fraud alert”).

5 (B) ISSUANCE AND PUBLICATION OF SPE-
6 CIAL FRAUD ALERTS.—Upon receipt of a re-
7 quest described in subparagraph (A), the In-
8 spector General shall investigate the subject
9 matter of the request to determine whether a
10 special fraud alert should be issued. If appro-
11 priate, the Inspector General shall in consulta-
12 tion with the Attorney General, issue a special
13 fraud alert in response to the request. All spe-
14 cial fraud alerts issued pursuant to this sub-
15 paragraph shall be published in the Federal
16 Register.

17 (2) CRITERIA FOR SPECIAL FRAUD ALERTS.—
18 In determining whether to issue a special fraud alert
19 upon a request described in paragraph (1), the In-
20 spector General may consider—

21 (A) whether and to what extent the prac-
22 tices that would be identified in the special
23 fraud alert may result in any of the con-
24 sequences described in subsection (a)(2); and

1 (B) the volume and frequency of the con-
2 duct that would be identified in the special
3 fraud alert.