

103^D CONGRESS
2^D SESSION

S. 2381

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

IN THE SENATE OF THE UNITED STATES

AUGUST 11, 1994

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

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.—

8 (A) SOLICITATION OF PROPOSALS FOR
9 SAFE HARBORS.—Not later than January 1,
10 1995, and not less than annually thereafter, the

1 Secretary of Health and Human Services (here-
2 after in this section referred to as the “Sec-
3 retary”) shall publish a notice in the Federal
4 Register soliciting proposals, which will be ac-
5 cepted during a 60-day period, for—

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

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

19 (iii) interpretive rulings to be issued
20 pursuant to subsection (b); and

21 (iv) special fraud alerts to be issued
22 pursuant to subsection (c).

23 (B) PUBLICATION OF PROPOSED MODI-
24 FICATIONS AND PROPOSED ADDITIONAL STATE
25 HARBORS.—After considering the proposals de-

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

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

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

7 (A) An increase or decrease in access to
8 health care services.

9 (B) An increase or decrease in the quality
10 of health care services.

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

13 (D) An increase or decrease in competition
14 among health care providers.

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

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

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

23 (H) The existence or nonexistence of any
24 potential financial benefit to a health care pro-

1 professional or provider which may vary based on
2 their decisions of—

3 (i) whether to order a health care
4 item or service; or

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

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

11 (b) INTERPRETIVE RULINGS.—

12 (1) IN GENERAL.—

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

21 (B) ISSUANCE AND EFFECT OF INTERPRE-
22 TIVE RULING.—

23 (i) IN GENERAL.—If appropriate, the
24 Inspector General shall in consultation
25 with the Attorney General, issue an inter-

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

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

18 (2) CRITERIA FOR INTERPRETIVE RULINGS.—

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

22 (i) whether and to what extent the re-
23 quest identifies an ambiguity within the
24 language of the statute, the existing safe

1 harbors, or previous interpretive rulings;
2 and

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

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

16 (c) SPECIAL FRAUD ALERTS.—

17 (1) IN GENERAL.—

18 (A) REQUEST FOR SPECIAL FRAUD
19 ALERTS.—Any person may present, at any
20 time, a request to the Inspector General for a
21 notice which informs the public of practices
22 which the Inspector General considers to be
23 suspect or of particular concern under section
24 1128B(b) of the Social Security Act (42 U.S.C.

1 1320a–7b(b)) (hereafter in this subsection re-
2 ferred to as a “special fraud alert”).

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

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

19 (A) whether and to what extent the prac-
20 tices that would be identified in the special
21 fraud alert may result in any of the con-
22 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.

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