

108TH CONGRESS
2D SESSION

H. R. 5311

To amend title XVIII of the Social Security Act to provide whistleblower protection to employees of clinical laboratories who furnish services under the Medicare Program, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 8, 2004

Mr. CUMMINGS introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, 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 amend title XVIII of the Social Security Act to provide whistleblower protection to employees of clinical laboratories who furnish services under 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.**

4 This Act may be cited as the “Clinical Laboratory
5 Compliance Improvement Act of 2004”.

1 **SEC. 2. PROTECTION OF EMPLOYEES OF PROVIDERS AND**
2 **SUPPLIERS OF CLINICAL DIAGNOSTIC LAB-**
3 **ORATORY TESTS WHO REPORT VIOLATIONS.**

4 (a) IN GENERAL.—Section 1846 of the Social Secu-
5 rity Act (42 U.S.C. 1395w–2) is amended by adding at
6 the end the following new subsection:

7 “(c)(1)(A) Each provider or clinical laboratory ap-
8 proved for participation under this title to provide clinical
9 diagnostic laboratory tests shall post in a conspicuous
10 place a notice to employees that indicates the manner in
11 which to report instances of noncompliance with condi-
12 tions of participation under this title of the provider or
13 laboratory (as the case may be), including deficiencies with
14 respect to testing, quality, and inadequately trained per-
15 sonnel.

16 “(B)(i) A notice under subparagraph (A) shall in-
17 clude—

18 “(I) the name and contact information of the
19 appropriate entity, accreditation organization, or
20 State or Federal agency to report instances of non-
21 compliance; and

22 “(II) a description of the rights and protections
23 under this section of individuals who report in-
24 stances of noncompliance.

25 “(ii) The Secretary shall specify the form of the no-
26 tice.

1 “(2)(A) A provider or clinical laboratory approved for
2 participation under this title to provide clinical diagnostic
3 laboratory tests shall not discriminate or retaliate in any
4 manner against any employee of the provider or laboratory
5 (as the case may be) because that employee, or any other
6 person, has presented a grievance or complaint, or has ini-
7 tiated or cooperated in any investigation or proceeding of
8 any kind, relating to the clinical diagnostic laboratory
9 tests performed by the provider or laboratory (as the case
10 may be) or other requirements and prohibitions of this
11 title.

12 “(B) An employee of a provider or clinical laboratory
13 approved for participation under this title to provide clin-
14 ical diagnostic laboratory tests who has been discriminated
15 or retaliated against in employment in violation of this
16 subsection may initiate judicial action in a United States
17 District Court and shall be entitled to reinstatement, reim-
18 bursement for lost wages and work benefits caused by the
19 unlawful acts of the employing provider or laboratory (as
20 the case may be). Prevailing employees are entitled to rea-
21 sonable attorney’s fees and costs associated with pursuing
22 the judicial action.

23 “(C) No action may be brought under subparagraph
24 (B) more than 2 years after the discrimination or retalia-
25 tion with respect to which the action is brought.

1 “(D) For purposes of this paragraph—

2 “(i) an adverse employment action shall be
3 treated as ‘retaliation or discrimination’; and

4 “(ii) an adverse employment action includes—

5 “(I) the failure to promote an individual or
6 provide any other employment-related benefit
7 for which the individual would otherwise be eli-
8 gible;

9 “(II) an adverse evaluation or decision
10 made in relation to accreditation, certification,
11 credentialing, or licensing of the individual; and

12 “(III) a personnel action that is adverse to
13 the individual concerned.”.

14 (b) CLERICAL AMENDMENT.—The heading of such
15 section is amended by adding at the end the following:

16 “; WHISTLEBLOWER PROTECTIONS”.

17 (c) EFFECTIVE DATE.—The amendment made by
18 subsection (a) shall take effect January 1, 2005.

19 **SEC. 3. REQUIREMENT FOR UNANNOUNCED SURVEYS.**

20 (a) IN GENERAL.—Section 1846 of the Social Secu-
21 rity Act (42 U.S.C. 1395w–2), as amended by section
22 2(a), is further amended by adding at the end the fol-
23 lowing new subsections:

24 “(d)(1) Upon receipt of a report of an instance of
25 noncompliance with conditions of participation by a pro-
26 vider or clinical laboratory approved for participation

1 under this title to provide clinical diagnostic laboratory
2 tests, the investigative organization shall—

3 “(A) provide notice to the Secretary and other
4 investigative organizations involved of receipt of the
5 report within 3 business days of such receipt using
6 a standard format and manner of transmission de-
7 veloped by the Secretary for such purpose;

8 “(B) promptly determine whether to investigate
9 the report; and

10 “(C) if appropriate, promptly investigate the report.

11 “(2) In measuring performance of an investigative or-
12 ganization under a contract entered into with the Sec-
13 retary, the Secretary shall provide for appropriate adjust-
14 ments to payments under the contract for failure to carry
15 out the responsibilities of this subsection.

16 “(3) In this subsection, the term ‘investigative orga-
17 nization’ means an accreditation organization, a State
18 agency, or other entity responsible for surveys of such pro-
19 viders or clinical laboratories.

20 “(e)(1) Each provider or clinical laboratory approved
21 for participation under this title to provide clinical diag-
22 nostic laboratory tests shall be subject to a standard sur-
23 vey, to be conducted without any prior notice to the pro-
24 vider or laboratory (as the case may be). Each survey shall

1 include verification of compliance with requirements under
 2 subsection (c).

3 “(2) Any individual who notifies (or causes to be noti-
 4 fied) a provider or laboratory of the time or date on which
 5 such a survey is scheduled to be conducted is subject to
 6 a civil money penalty not to exceed \$2,000.

7 “(3) The Secretary shall review each State’s proce-
 8 dures for the scheduling and conduct of standard surveys
 9 to assure that the State has taken all reasonable steps
 10 to avoid giving notice of such a survey through the sched-
 11 uling procedures and the conduct of the surveys them-
 12 selves.

13 “(f) The Secretary shall submit to Congress an an-
 14 nual report on the actions taken under this section. Each
 15 such report shall include information on reports made
 16 under subsection (c), actions taken under subsection (d),
 17 the promptness with which such actions were taken, the
 18 findings of any investigation of such reports, and any ac-
 19 tions taken based upon such findings.”.

20 (b) CLERICAL AMENDMENT.—The heading of such
 21 section, as amended by section 2(b), is further amended
 22 by adding at the end the following:

23 “; UNANNOUNCED SURVEYS”.

24 (c) EFFECTIVE DATE.—The amendment made by
 25 subsection (a) shall take effect January 1, 2005.