

104TH CONGRESS
1ST SESSION

H. R. 1386

To amend section 353 of the Public Health Service Act to exempt physician office laboratories from the clinical laboratories requirements of that section.

IN THE HOUSE OF REPRESENTATIVES

APRIL 4, 1995

Mr. ARCHER introduced the following bill; which was referred to the
Committee on Commerce

A BILL

To amend section 353 of the Public Health Service Act to exempt physician office laboratories from the clinical laboratories requirements of that section.

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 Improvement Act Amendments of 1995”.

6 **SEC. 2. EXEMPTION OF PHYSICIAN OFFICE LABORATORIES.**

7 Section 353(d) of the Public Health Service Act (42
8 U.S.C. 263a(d)) is amended—

1 (1) by redesignating paragraphs (2), (3), and
2 (4) as paragraphs (3), (4), and (5) and by adding
3 after paragraph (1) the following:

4 “(4) EXEMPTION OF PHYSICIAN OFFICE LAB-
5 ORATORIES.—

6 “(A) IN GENERAL.—Except as provided in
7 subparagraph (B), a clinical laboratory in a
8 physician’s office (including an office of a group
9 of physicians) which is directed by a physician
10 and in which examinations and procedures are
11 either performed by a physician or by individ-
12 uals supervised by a physician solely as an ad-
13 junct to other services provided by the physi-
14 cian’s office is exempt from this section.

15 “(B) EXCEPTION.—A clinical laboratory
16 described in subparagraph (A) is not exempt
17 from this section when it performs a pap smear
18 (Papanicolaous Smear) analysis.

19 “(C) DEFINITION.—For purposes of sub-
20 paragraph (A), the term ‘physician’ has the
21 same meaning as is prescribed for such term by
22 section 1861(r) of the Social Security Act (42
23 U.S.C. 1395x(r)).”;

24 (2) in paragraph (3) (as so redesignated) by
25 striking “(3)” and inserting “(4)”; and

1 (3) in paragraphs (4) and (5) (as so redesignated)
2 nated) by striking “(2)” and inserting “(3)”.

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