106TH CONGRESS
1ST SESSION

H. R. 528

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

FEBRUARY 3, 1999

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

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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 1999".

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   "(2) 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   (Papanicolaou 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 redesig-

2   nated) by striking "(2)" and inserting "(3)".

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