

105TH CONGRESS  
1ST SESSION

# S. 1068

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 SENATE OF THE UNITED STATES

JULY 25, 1997

Mrs. HUTCHISON (for herself, Mr. COCHRAN, Mr. FAIRCLOTH, and Mr. NICKLES) introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

---

## 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 1997”.

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), respectively;

3 (2) by inserting after paragraph (1) the follow-  
 4 ing:

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

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

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

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

1           (3) in subparagraphs (A) and (B) of paragraph  
2       (3) (as so redesignated) by striking “paragraph (3)”  
3       each place that such term appears and inserting  
4       “paragraph (4)”; and  
5           (4) in paragraphs (4) and (5) (as so redesign-  
6       nated), by striking “paragraph (2)” each place that  
7       such appears and inserting “paragraph (3)”.

○