

Union Calendar No. 348

110TH CONGRESS
2^D SESSION

H. R. 1237

[Report No. 110-566]

To amend the Public Health Service Act to provide revised standards for quality assurance in screening and evaluation of gynecologic cytology preparations, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 28, 2007

Mr. GORDON of Tennessee (for himself, Mr. PRICE of Georgia, Ms. FOXX, Ms. HERSETH, and Mr. DEAL of Georgia) introduced the following bill; which was referred to the Committee on Energy and Commerce

APRIL 8, 2008

Additional sponsors: Mr. ROGERS of Michigan, Mr. BURGESS, Mr. COHEN, Mr. ENGLISH of Pennsylvania, Mr. JEFFERSON, Mr. BOUCHER, Mrs. MYRICK, Mr. GENE GREEN of Texas, Mr. HOLDEN, Ms. HOOLEY, Mr. BURTON of Indiana, Mr. SHUSTER, Mr. HINOJOSA, Mr. MCNULTY, Mr. SHIMKUS, Mr. WELDON of Florida, Mr. BOUSTANY, Mr. GONZALEZ, Mr. BOSWELL, Mr. SULLIVAN, Ms. BALDWIN, Mr. DOYLE, Mr. LATHAM, Mr. RYAN of Wisconsin, Mr. BONNER, Mr. NEAL of Massachusetts, Mrs. CUBIN, Mr. COBLE, Mr. PAUL, Mr. TIM MURPHY of Pennsylvania, Mr. PITTS, Mr. YOUNG of Alaska, Mr. DAVID DAVIS of Tennessee, Mrs. MALONEY of New York, Mr. ROTHMAN, Mr. SIRES, Mr. GINGREY, Mrs. MCCARTHY of New York, Mr. PICKERING, Mr. WYNN, Mr. MCGOVERN, Ms. ROYBAL-ALLARD, Mr. WEINER, Mrs. BLACKBURN, Mr. SNYDER, Ms. DEGETTE, Mr. MORAN of Virginia, Ms. ESHOO, Mr. BUTTERFIELD, Mrs. CAPP, Mr. CARNAHAN, Mr. HARE, Mrs. BONO MACK, Mr. RENZI, Mr. ABERCROMBIE, Mr. PLATTS, Mr. ALLEN, Mr. HILL, Mr. ROSS, Ms. HARMAN, Mr. BUYER, Mr. RAMSTAD, Ms. WOOLSEY, Mr. DONNELLY, Mr. KILDEE, Mr. HALL of Texas, Mr. HIGGINS, Mr. LINCOLN DIAZ-BALART of Florida, Ms. SLAUGHTER, Mr. BAIRD, Mr. FERGUSON, Mrs. WILSON of New Mexico, Mr. MANZULLO, Mr. BRALEY of Iowa, Mr. ENGEL, Mr. BERRY, Mr. BOOZMAN, Mr. WOLF, Mr. PAYNE, Mr. FORTUÑO, Mr. DAVIS of Illinois, Mr. TERRY, Mr. KIND, Mr. MELANCON, Mrs. JO ANN DAVIS of Virginia, Mr. NADLER, Mr. HERGER, Mr. KAGEN, Mr. REY-

NOLDS, Mr. ALTMIRE, Mr. HINCHEY, Mr. KENNEDY, Mr. LEVIN, Ms. SCHAKOWSKY, Mr. RADANOVICH, Mr. BILIRAKIS, Mr. FOSSELLA, Mr. MARKEY, Mr. LEWIS of Georgia, Mr. TIBERI, Mr. BARROW, Mr. PASCRELL, Mr. CASTLE, Mr. UPTON, Ms. SOLIS, Mr. ISSA, Ms. KAPTUR, Mr. HALL of New York, Mr. WHITFIELD of Kentucky, Mr. MEEK of Florida, Mr. LANGEVIN, Mr. INSLEE, Mr. WAXMAN, Mr. MATHESON, Mr. THOMPSON of Mississippi, Mr. SENSENBRENNER, Mr. KING of New York, Mr. COURTNEY, Ms. BERKLEY, Mr. PETRI, Mr. LARSON of Connecticut, Mr. SCOTT of Georgia, Ms. SCHWARTZ, Mr. KIRK, Mr. UDALL of New Mexico, Mr. TOWNS, Mr. CAMP of Michigan, Mrs. BOYDA of Kansas, Mr. STUPAK, Ms. GINNY BROWN-WAITE of Florida, Mr. BERMAN, Ms. ZOE LOFGREN of California, Mr. WALDEN of Oregon, Mr. BISHOP of Georgia, Mr. JOHNSON of Illinois, Mr. COSTELLO, Mr. CALVERT, Ms. RICHARDSON, Mr. STEARNS, Mr. OLVER, Mr. WALSH of New York, Mr. AL GREEN of Texas, Mrs. GILLIBRAND, Mr. LOBIONDO, Mr. KUHLMAN of New York, Mr. BRADY of Pennsylvania, Mr. MCINTYRE, Mr. WELCH of Vermont, Mr. SHADEGG, Mr. BUCHANAN, Mrs. CHRISTENSEN, Mr. DENT, Ms. SUTTON, Mrs. JONES of Ohio, Mr. SHAYS, Mr. FATTAH, Ms. MOORE of Wisconsin, Ms. DELAURO, Mr. PORTER, Mr. MURPHY of Connecticut, Mr. SAM JOHNSON of Texas, Ms. CLARKE, Mr. LYNCH, Mr. RUSH, Mr. LATOURETTE, Mr. EHLERS, Ms. TSONGAS, Mr. HOEKSTRA, Mr. BOREN, Mr. FEENEY, and Ms. SHEA-PORTER

APRIL 8, 2008

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

To amend the Public Health Service Act to provide revised standards for quality assurance in screening and evaluation of gynecologic cytology preparations, 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 “Cytology Proficiency~~
 5 ~~Improvement Act of 2007”.~~

1 **SEC. 2. REVISED STANDARDS FOR QUALITY ASSURANCE IN**
2 **SCREENING AND EVALUATION OF**
3 **GYNECOLOGIC CYTOLOGY PREPARATIONS.**

4 (a) **IN GENERAL.**—Section 353(f)(4)(B)(iv) of the
5 Public Health Service Act (42 U.S.C. 263a(f)(4)(B)(iv))
6 is amended to read as follows:

7 “(iv) requirements that each clinical
8 laboratory—

9 “(I) ensure that all individuals
10 involved in screening and interpreting
11 cytological preparations at the labora-
12 tory participate annually in a con-
13 tinuing medical education program in
14 gynecologic cytology that—

15 “(aa) is approved by the Ac-
16 crediting Council for Continuing
17 Medical Education or the Amer-
18 ican Academy of Continuing
19 Medical Education; and

20 “(bb) provides each indi-
21 vidual participating in the pro-
22 gram with gynecologic cytologic
23 preparations (in the form of ref-
24 erenced glass slides or equivalent
25 technologies) designed to improve
26 the locator, recognition and inter-

1 pretive skills of the individual;
2 and

3 “(H) maintain a record of the cy-
4 tology continuing medical education
5 results of each individual involved in
6 screening and interpreting cytological
7 preparations at the laboratory.”

8 (b) EFFECTIVE DATE AND IMPLEMENTATION; TER-
9 MINATION OF CURRENT PROGRAM OF INDIVIDUAL PRO-
10 FICIENCY TESTING.—

11 (1) EFFECTIVE DATE AND IMPLEMENTATION.—

12 Except as provided in paragraph (2), the amend-
13 ment made by subsection (a) applies to gynecologic
14 cytology services provided on or after the date that
15 is one year after the date of the enactment of this
16 Act, and the Secretary of Health and Human Serv-
17 ices (hereafter in this subsection referred to as the
18 “Secretary”) shall issue final regulations imple-
19 menting such amendment not later than 270 days
20 after such date of enactment.

21 (2) TERMINATION OF CURRENT INDIVIDUAL
22 PROFICIENCY TESTING PROGRAM.—As of the date of
23 the enactment of this Act, the Secretary shall termi-
24 nate the individual proficiency testing program es-
25 tablished pursuant to section 353(f)(4)(B)(iv) of the

1 Public Health Service Act (42 U.S.C.
2 263a(f)(4)(B)(iv)), as in effect before the enactment
3 of this section.

4 **SECTION 1. SHORT TITLE.**

5 *This Act may be cited as the “Cytology Proficiency*
6 *Improvement Act of 2008”.*

7 **SEC. 2. REVISED STANDARDS FOR QUALITY ASSURANCE IN**
8 **SCREENING AND EVALUATION OF**
9 **GYNECOLOGIC CYTOLOGY PREPARATIONS.**

10 *(a) IN GENERAL.—Section 353(f)(4)(B)(iv) of the Pub-*
11 *lic Health Service Act (42 U.S.C. 263a(f)(4)(B)(iv)) is*
12 *amended to read as follows:*

13 *“(iv) requirements that each clinical*
14 *laboratory—*

15 *“(I) ensure that all individuals*
16 *involved in screening and interpreting*
17 *cytological preparations at the labora-*
18 *tory participate annually in a con-*
19 *tinuing medical education program in*
20 *gynecologic cytology that—*

21 *“(aa) is approved by the Ac-*
22 *crediting Council for Continuing*
23 *Medical Education or the Amer-*
24 *ican Academy of Continuing Med-*
25 *ical Education; and*

1 “(bb) provides each indi-
2 vidual participating in the pro-
3 gram with gynecologic cytological
4 preparations (in the form of ref-
5 erenced glass slides or equivalent
6 technologies) designed to improve
7 the locator, recognition, and inter-
8 pretive skills of the individual;

9 “(II) maintain a record of the cy-
10 tology continuing medical education
11 program results for each individual in-
12 volved in screening and interpreting
13 cytological preparations at the labora-
14 tory;

15 “(III) provide that the laboratory
16 director shall take into account such
17 results and other performance metrics
18 in reviewing the performance of indi-
19 viduals involved in screening and in-
20 terpreting cytological preparations at
21 the laboratory and, when necessary,
22 identify needs for remedial training or
23 a corrective action plan to improve
24 skills; and

1 “(IV) submit the continuing edu-
2 cation program results for each indi-
3 vidual and, if appropriate, plans for
4 corrective action or remedial training
5 in a timely manner to the laboratory’s
6 accrediting organization for purposes
7 of review and on-going monitoring by
8 the accrediting organization, including
9 reviews of the continuing medical edu-
10 cation program results during on-site
11 inspections of the laboratory.”.

12 (b) *EFFECTIVE DATE AND IMPLEMENTATION; TERMI-*
13 *NATION OF CURRENT PROGRAM OF INDIVIDUAL PRO-*
14 *FICIENCY TESTING.—*

15 (1) *EFFECTIVE DATE AND IMPLEMENTATION.—*
16 *Except as provided in paragraph (2), the amendment*
17 *made by subsection (a) applies to gynecologic cytology*
18 *services provided on or after the first day of the first*
19 *calendar year beginning 1 year or more after the date*
20 *of the enactment of this Act, and the Secretary of*
21 *Health and Human Services (hereafter in this sub-*
22 *section referred to as the “Secretary”) shall issue final*
23 *regulations implementing such amendment not later*
24 *than 270 days after such date of enactment.*

1 (2) *TERMINATION OF CURRENT INDIVIDUAL*
2 *TESTING PROGRAM.—The Secretary of Health and*
3 *Human Services shall terminate the individual pro-*
4 *ficiency testing program established pursuant to sec-*
5 *tion 353(f)(4)(B)(iv) of the Public Health Service Act*
6 *(42 U.S.C. 263a(f)(4)(B)(iv)), as in effect on the day*
7 *before the date of the enactment of subsection (a), at*
8 *the end of the calendar year which includes the date*
9 *of enactment of the amendment made by subsection*
10 *(a).*

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