

Thurs 7/30
9:31 am
B

**AMENDMENT TO THE AMENDMENT IN THE
NATURE OF A SUBSTITUTE TO H.R. 3200
OFFERED BY MS. BALDWIN OF WISCONSIN
(AINS-EC_001)**

In section 1150A(c) of such Act, as added by section 1905—

(1) redesignate paragraphs (7) and (8) as paragraphs (9) and (10), respectively; and

(2) insert after paragraph (6) the following new paragraphs:

1 “(7) Support for coordination of State and Fed-
2 eral contracting and oversight for dual coordination
3 programs supportive of the goals described in sub-
4 section (b);

5 “(8) Support for State Medicaid agencies
6 through the provision of technical assistance for
7 Medicare and Medicaid coordination initiatives de-
8 signed to improve acute and long-term care for dual
9 eligibles;

In section 1150A, as added by section 1905—

(1) redesignate subsections (d) and (e) as subsection (f) and (g), respectively;

(2) in subsection (a), strike “as defined in subsection (e)” and insert “as defined in subsection (g)”;

(3) insert after subsection (c) the following new subsections:

1 “(d) INTEGRATED REPORTING; BENCHMARKS.—

2 “(1) IN GENERAL.—The Office or program
3 shall work with relevant State agencies to establish
4 a common set of risk adjusted quality measures and
5 reporting procedures for Medicare and Medicaid re-
6 porting that include integration and consolidation of
7 current reporting requirements for—

8 “(A) annual risk assessment and model of
9 care requirements;

10 “(B) the Healthcare Effectiveness Data
11 and Information Set (HEDIS), Consumer As-
12 sessment of Healthcare Providers and Systems
13 (CAHPS), Health Outcomes Study (HOS),
14 Quality Improvement Projects (QIP), Chronic
15 Care Improvement Program (CCIP), and any
16 plan organizational structure and quality im-
17 provement processes; and

18 “(C) a common set of risk adjusted bench-
19 marks for Medicare and Medicaid to evaluate
20 performance of for integrated Medicare-Med-

1 icaid programs for dual eligibles in serving a
2 comparable group of beneficiaries under the
3 original Medicare fee-for-service program, under
4 the Medicare Advantage program, and under
5 Medicaid managed care, including, to the extent
6 possible, the following outcomes measures:
7 emergency room use, avoidable hospitalizations
8 and inpatient readmissions for ambulatory care
9 sensitive conditions; medication management to
10 prevent adverse drug events and promote ad-
11 herence; long-term nursing home stays; bene-
12 ficiary satisfaction; and such other measures as
13 the Secretary deems appropriate.

14 “(c) CONSULTATION WITH STAKEHOLDERS.—The
15 Office or program shall consult with relevant stakeholders,
16 including representatives for dual eligible beneficiaries,
17 health plans, providers, and State Medicaid agencies, in
18 the development of policies related to integrated Medicare-
19 Medicaid programs for dual eligibles.

 In section 1177, strike subsection (b) and insert the
following:

20 (b) EXTENSION OF CERTAIN PLANS.—

21 (1) PLANS DESCRIBED.—For purposes of Sec-
22 tion 1859(f)(1) of the Social Security Act (42
23 U.S.C. 1395w-28(f)(1)), a plan described in this

1 paragraph is a Medicare Advantage dual eligible spe-
2 cial needs plan that—

3 (A) whose sponsoring Medicare Advantage
4 organization, as of the date enactment of Amer-
5 ica's Affordable Health Choices Act of 2009,
6 has a contract with a State Medicaid Agency
7 that participated in the "Demonstrations Serv-
8 ing Those Dually-Eligible for Medicare and
9 Medicaid" under the Medicare program; and

10 (B) that has been approved by the Centers
11 for Medicare & Medicaid Services as a dual eli-
12 gible special needs plan and that offers inte-
13 grated Medicare and Medicaid services under a
14 contract with the State Medicaid agency.

15 (2) ANALYSIS; REPORT.—

16 (A) ANALYSIS.—The Secretary of Health
17 and Human Services shall provide, through a
18 contract with an independent health services
19 evaluation organization, for an analysis of the
20 plans described in paragraph (1) with regard to
21 the impact of such plans on cost, quality of
22 care, patient satisfaction, and other subjects
23 specified by the Secretary. Such report also will
24 identify statutory changes needed to simplify
25 access to needed services, improve coordination

1 of benefits and services and ensure protection
2 for dual eligibles as appropriate.

3 (B) REPORT.—Not later than December
4 31, 2011, the Secretary shall submit to the
5 Congress a report on the analysis under sub-
6 paragraph (A) and shall include in such report
7 such recommendations with regard to the treat-
8 ment of such plans as the Secretary deems ap-
9 propriate.



11:59 am Mon

A

AMENDMENT
OFFERED BY MR. BUTTERFIELD OF NORTH
CAROLINA

(Amendment drafted to file AINS-EC_001)

At the end of section 122, add the following new subsection:

1 (d) REPORT REGARDING INCLUSION OF ORAL
2 HEALTH CARE IN ESSENTIAL BENEFITS PACKAGE.—Not
3 later than one year after the date of the enactment of this
4 Act, the Secretary of Health and Human Services shall
5 submit to Congress a report containing the results of a
6 study determining the need and cost of providing acces-
7 sible and affordable oral health care to adults as part of
8 the essential benefits package.



1 costs attributable to the qualified wellness program
2 and not to the health plan, or health insurance cov-
3 erage offered in connection with such a plan, may be
4 taken into account.

5 “(2) LIMITATION.—The amount of the grant
6 allowed under paragraph (1) for any plan year shall
7 not exceed the sum of—

8 “(A) the product of \$200 and the number
9 of employees of the employer not in excess of
10 200 employees; plus

11 “(B) the product of \$100 and the number
12 of employees of the employer in excess of 200
13 employees.

14 The wellness grants awarded to an employer under
15 this section shall be for up to 3 years and shall not
16 exceed \$50,000.

17 “(b) QUALIFIED WELLNESS PROGRAM.—For pur-
18 poses of this section:

19 “(1) QUALIFIED WELLNESS PROGRAM.—The
20 term ‘qualified wellness program’ means a program
21 that —

22 “(A) includes any 3 wellness components
23 described in subsection (c); and

24 “(B) is be certified by the Secretary, in co-
25 ordination with the Health Choices Commis-

1 sioner and the Director of the Center for Dis-
2 ease Control and Prevention, as a qualified
3 wellness program under this section.

4 “(2) PROGRAMS MUST BE CONSISTENT WITH
5 RESEARCH AND BEST PRACTICES.—

6 “(A) IN GENERAL.—The Secretary shall
7 not certify a program as a qualified wellness
8 program unless the program—

9 “(i) is newly established or in exist-
10 ence on the date of enactment of this Act
11 but not yet meeting the requirements of
12 this section;

13 “(ii) is consistent with evidenced-
14 based researched and best practices, as
15 identified by persons with expertise in em-
16 ployer health promotion and wellness pro-
17 grams;

18 “(iii) includes multiple, evidenced-
19 based strategies which are based on the ex-
20 isting and emerging research and careful
21 scientific reviews, including the Guide to
22 Community Preventative Services, the
23 Guide to Clinical Preventative Services,
24 and the National Registry for Effective
25 Programs, and

1 “(iv) includes strategies which focus
2 on prevention and support for employee
3 populations at risk of poor health out-
4 comes.

5 “(B) PERIODIC UPDATING AND REVIEW.—
6 The Secretary , in consultation with other ap-
7 propriate agencies shall establish procedures for
8 periodic review, evaluation, and update of the
9 programs under this subsection.

10 “(3) HEALTH LITERACY/ACCESSIBILITY.—The
11 Secretary shall, as part of the certification process—

12 “(A) ensure that employers make the pro-
13 grams culturally competent. physically and pro-
14 grammatically accessible (including for individ-
15 uals with disabilities), and appropriate to the
16 health literacy needs of the employees covered
17 by the programs;

18 “(B) require a health literacy component
19 to provide special assistance and materials to
20 employees with low literacy skills, limited
21 English and from under-served populations; and

22 “(C) require the Secretary , in consultation
23 with Secretary of Labor, to compile and dis-
24 seminate to employer health plans info on

1 model health literacy curricula, instructional
2 programs, and effective intervention strategies.

3 “(c) WELLNESS PROGRAM COMPONENTS.—For pur-
4 poses of this section, the wellness program components de-
5 scribed in this subsection are the following:

6 “(1) HEALTH AWARENESS COMPONENT.—A
7 health awareness component which provides for the
8 following:

9 “(A) HEALTH EDUCATION.—The dissemi-
10 nation of health information which addresses
11 the specific needs and health risks of employees.

12 “(B) HEALTH SCREENINGS.—The oppor-
13 tunity for periodic screenings for health prob-
14 lems and referrals for appropriate follow up
15 measures.

16 “(2) EMPLOYEE ENGAGEMENT COMPONENT.—
17 An employee engagement component which provides
18 for the active engagement of employees in worksite
19 wellness programs through worksite assessments and
20 program planning, onsite delivery, evaluation, and
21 improvement efforts.

22 “(3) BEHAVIORAL CHANGE COMPONENT.—A
23 behavioral change component which provides for al-
24 tering employee lifestyles to encourage healthy living
25 through counseling, seminars, on-line programs, or

1 self-help materials which provide technical assistance
2 and problem solving skills. such component may in-
3 clude programs relating to—

4 “(A) tobacco use;

5 “(B) obesity;

6 “(C) stress management;

7 “(D) physical fitness;

8 “(E) nutrition;

9 “(F) substance abuse;

10 “(G) depression; and

11 “(H) mental health promotion (including
12 anxiety).

13 “(4) SUPPORTIVE ENVIRONMENT COMPO-

14 NENT.—A supportive environment component which
15 includes the following:

16 “(A) ON-SITE POLICIES.—Policies and
17 services at the worksite which promote a
18 healthy lifestyle, including policies relating to—

19 “(i) tobacco use at the worksite;

20 “(ii) the nutrition of food available at
21 the worksite through cafeterias and vend-
22 ing options;

23 “(iii) minimizing stress and promoting
24 positive mental health in the workplace;
25 and

1 “(iv) the encouragement of physical
2 activity before, during, and after work
3 hours.

4 “(d) PARTICIPATION REQUIREMENT.—No grant shall
5 be allowed under subsection (a) unless the Secretary in
6 consultation with other appropriate agencies, certifies, as
7 a part of any certification described in subsection (b), that
8 each wellness program component of the qualified wellness
9 program—

10 “(1) shall be available to all employees of the
11 employer;

12 “(2) shall not mandate participation by employ-
13 ees; and

14 “(3) shall not require participation by indi-
15 vidual employees as a condition to obtain a premium
16 discount, rebate, deductible reduction, or other fi-
17 nancial reward.

18 “(e) PRIVACY PROTECTIONS.—Any employee health
19 information collected through participation in an employer
20 wellness program shall be confidential and available only
21 to appropriately trained health professions as defined by
22 the Secretary . Employers or employees of the employer
23 sponsoring a wellness program shall have no access to em-
24 ployee health data. All entities offering employer-spon-
25 sored wellness programs shall be considered ‘business as-

1 sociates' pursuant to the American Reinvestment and Re-
2 covery Act and must comply with privacy protections re-
3 stricting the release of personal medical information.

4 “(f) DEFINITIONS AND SPECIAL RULES.—For pur-
5 poses of this section:

6 “(1) QUALIFIED EMPLOYER.—The term ‘quali-
7 fied employer’ means an employer that offers a
8 qualified health benefits plan to every employee (in-
9 cluding each employee required to be offered cov-
10 erage under a qualified health benefits plan under
11 subtitle B of title III of division A of the America’s
12 Affordable Health Choices Act of 2009), and meets
13 the health coverage participation requirements as de-
14 fined in section 312 of such Act.

15 “(2) CERTAIN COSTS NOT INCLUDED.—Costs
16 paid or incurred by an employer for food or health
17 insurance shall not be taken into account under sub-
18 section (a).

19 “(g) OUTREACH.—

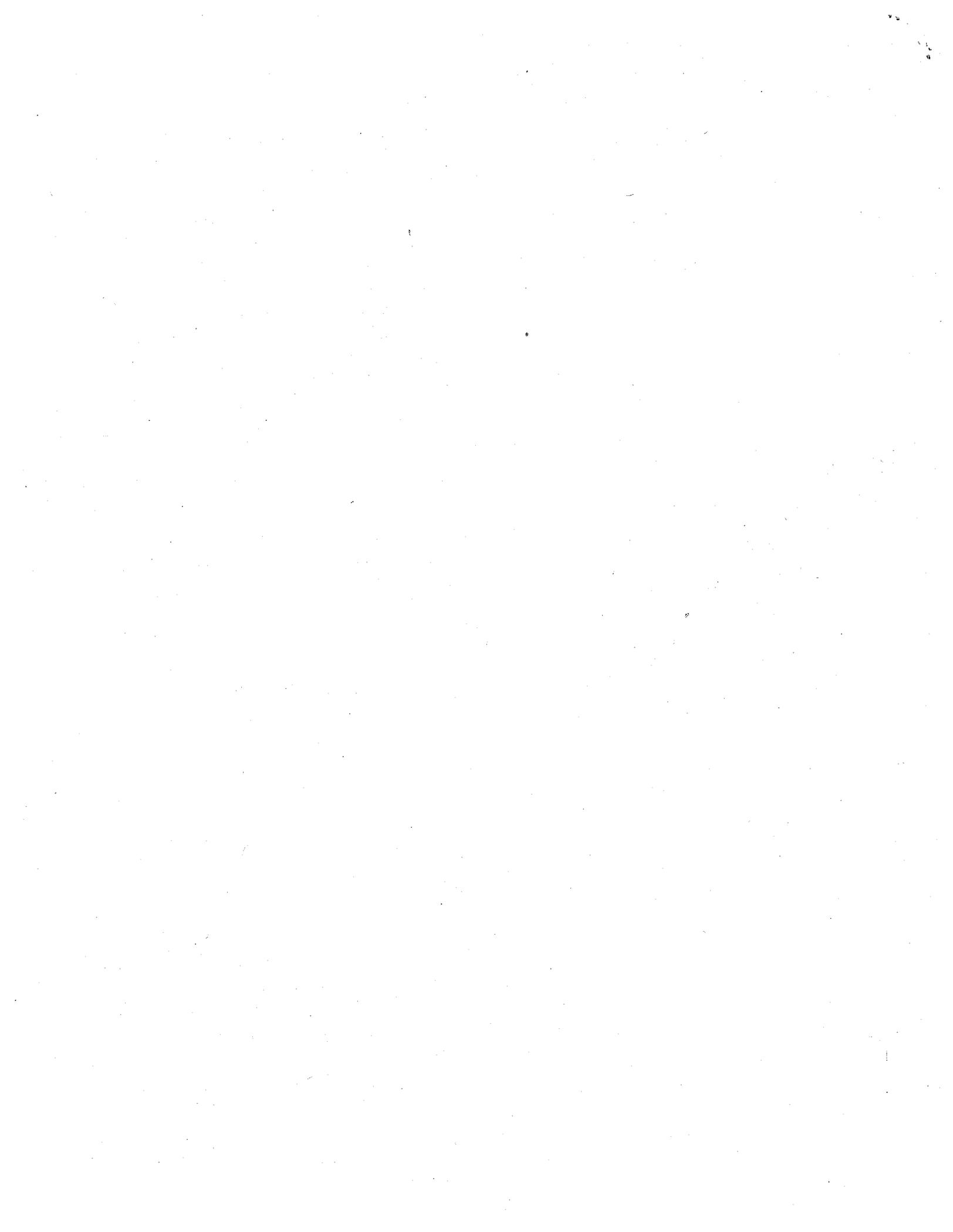
20 “(1) IN GENERAL.—The Secretary, in conjunc-
21 tion with other appropriate agencies and members of
22 the business community, shall institute an outreach
23 program to inform businesses about the availability
24 of the wellness program grant as well as to educate
25 businesses on how to develop programs according to

1 recognized and promising practices and on how to
2 measure the success of implemented programs.

3 “(h) EFFECTIVE DATE.—This section shall take ef-
4 fect on January 1, 2013.

5 “(i) AUTHORIZATION OF APPROPRIATIONS.—There
6 are authorized to be appropriated such sums as are nec-
7 essary to carry out this section.”





7/31 For
10:48 am
C

AMENDMENT

OFFERED BY MR. GENE GREEN OF TEXAS

At the appropriate place in division ____, insert the following:

1 **SEC. ____ . GRANTS TO STRENGTHEN THE EFFECTIVENESS,**
2 **EFFICIENCY, AND COORDINATION OF SERV-**
3 **ICES.**

4 (a) **IN GENERAL.**—The Secretary of Health and
5 Human Services (in this Act referred to as the “Sec-
6 retary”) shall award grants to assist in the development
7 of integrated health care delivery systems to serve defined
8 communities of individuals—

9 (1) to improve the efficiency of and coordina-
10 tion among the providers providing services through
11 such systems;

12 (2) to assist local communities in developing
13 programs targeted toward preventing and managing
14 chronic diseases; and

15 (3) to expand and enhance the services provided
16 through such systems.

17 (b) **ELIGIBLE ENTITIES.**—To be eligible to receive a
18 grant under this section, an entity shall be an entity
19 that—

1 (1) represents a balanced consortium—

2 (A) whose principal purpose is to ensure
3 the sustainable capacity for the provision of a
4 broad range of coordinated services for all resi-
5 dents within a community defined in the enti-
6 ty's grant application as described in paragraph
7 (2); and

8 (B) that includes at least one of each of
9 the following providers that serve the commu-
10 nity (unless such provider does not exist within
11 the community, declines or refuses to partici-
12 pate, or places unreasonable conditions on their
13 participation)—

14 (i) a Federally qualified health center
15 (as defined in section 1861(aa) of the So-
16 cial Security Act (42 U.S.C. 1395x(aa)));

17 (ii) rural health clinics and rural
18 health networks (as defined in sections
19 1861(aa) and 1820(d) of the Social Secu-
20 rity Act, respectively (42 U.S.C.
21 1395x(aa), 1395i-4(d)));

22 (iii) a hospital with a low-income utili-
23 zation rate that is greater than 25 percent
24 (as defined in section 1923(b)(3) of the
25 Social Security Act (42 U.S.C. 1396r-

1 4(b)(3))) or a critical access hospital (as
2 defined in section 1820(c)(2) of the Social
3 Security Act (42 U.S.C. 1395i-4(e)(2)));

4 (iv) a public health department; and

5 (v) an interested public or private sec-
6 tor health care provider or an organization
7 that has traditionally served the medically
8 uninsured and low-income individuals; and

9 (2) submits to the Secretary an application, in
10 such form and manner as the Secretary shall pre-
11 scribe, that—

12 (A) clearly defines the community to be
13 served;

14 (B) identifies the providers who will par-
15 ticipate in the community coalition under the
16 grant and specifies each provider's contribution
17 to the care of individuals in the community;

18 (C) describes the activities that the appli-
19 cant and the community coalition propose to
20 perform under the grant to further the objec-
21 tives of this section;

22 (D) demonstrates that it is an established
23 coalition with ability to build on the current
24 system for serving the community by involving
25 providers who have traditionally provided a sig-

1 nificant volume of care for uninsured and low-
2 income individuals for that community;

3 (E) demonstrates the coalition's ability to
4 develop coordinated systems of care that either
5 directly provide or ensure the prompt provision
6 of a broad range of high-quality, accessible
7 services, including, as appropriate, primary, sec-
8 ondary, and tertiary services as well as phar-
9 macy, substance abuse, behavioral health and
10 oral health services, in a manner that ensures
11 continuity of care in the community;

12 (F) provides evidence of community in-
13 volvement, including the business community, in
14 the development, implementation, and direction
15 of the system of care that the coalition proposes
16 to ensure;

17 (G) demonstrates the coalition's ability to
18 ensure that participating individuals are en-
19 rolled in health care coverage programs, both
20 public and private, for which the individuals are
21 eligible;

22 (H) presents a plan for leveraging other
23 sources of revenue, which may include State
24 and local sources and private grant funds, and
25 integrating current and proposed new funding

1 sources in a manner to ensure long-term sus-
2 tainability of the system of care;

3 (I) describes a plan for evaluation of the
4 activities carried out under the grant, including
5 measurement of progress toward the goals and
6 objectives of the program and the use of evalua-
7 tion findings to improve system performance;

8 (J) demonstrates fiscal responsibility
9 through the use of appropriate accounting pro-
10 cedures and management systems;

11 (K) demonstrates commitment to serve the
12 community without regard to the ability of an
13 individual or family to pay by arranging for or
14 providing free or reduced charge care for the
15 poor; and

16 (L) includes such other information as the
17 Secretary may prescribe.

18 (c) LIMITATIONS.—

19 (1) IN GENERAL.—An eligible entity may re-
20 ceive a grant under this section for 3 consecutive fis-
21 cal years and may receive such a grant award for 2
22 additional years if—

23 (A) the eligible entity submits to the Sec-
24 retary a request for a grant for such additional
25 years;

1 (B) the Secretary determines that current
2 performance justifies the granting of such a re-
3 quest; and

4 (C) the Secretary determines that granting
5 such request is necessary to further the objec-
6 tives described in subsection (a).

7 (d) PRIORITIES.—In awarding grants under this sec-
8 tion, the Secretary—

9 (1) may accord priority to applicants that dem-
10 onstrate the greatest extent of unmet need in the
11 community for a more coordinated system of care;
12 and

13 (2) shall accord priority to applicants that best
14 promote the objectives of this section, taking into
15 consideration the extent to which the applicant—

16 (A) identifies a community whose geo-
17 graphical area has a high or increasing percent-
18 age of individuals who are uninsured or low-in-
19 come;

20 (B) demonstrates that the applicant has
21 included in its community coalition providers,
22 support systems, and programs that have a tra-
23 dition of serving individuals and families in the
24 community who are uninsured or earn below
25 200 percent of the Federal poverty level;

1 (C) shows evidence that the proposed coali-
2 tion activities would expand utilization of pre-
3 ventive and primary care services for uninsured
4 and underinsured individuals and families in
5 the community, including pharmaceuticals, be-
6 havioral and mental health services, oral health
7 services, or substance abuse services;

8 (D) proposes approaches that would im-
9 prove coordination between health care pro-
10 viders and appropriate social service providers;

11 (E) demonstrates collaboration with State
12 and local governments;

13 (F) demonstrates that the applicant makes
14 use of non-Federal contributions to the greatest
15 extent possible; or

16 (G) demonstrates likelihood that the pro-
17 posed activities will lead to sustainable inte-
18 grated delivery system as additional efforts of
19 health systems development evolve.

20 (e) USE OF FUNDS.—

21 (1) USE BY GRANTEES.—

22 (A) IN GENERAL.—Except as provided in
23 paragraphs (2) and (3), a grantee may use
24 amounts provided under this section only for—

1 (i) direct expenses associated with
2 achieving the greater integration of a
3 health care delivery system so that the sys-
4 tem either directly provides or ensures the
5 provision of a broad range of culturally
6 competent services, including as appro-
7 priate primary, secondary, and tertiary
8 care and oral health, substance abuse, be-
9 havioral and mental health, and pharma-
10 ceutical services; and

11 (ii) direct patient care and service ex-
12 pansions to fill identified or documented
13 gaps within an integrated delivery system.

14 (B) SPECIFIC USES.—The following are ex-
15 amples of purposes for which a grantee may use
16 grant funds under this section, when such use
17 meets the conditions stated in subparagraph

18 (A):

19 (i) Increases in outreach activities and
20 closing gaps in health care service, includ-
21 ing referral to specialty services and pre-
22 scription drugs and conducting ongoing
23 outreach to health disparity populations.

- 1 (ii) Improvements to care manage-
2 ment and delivery of patient-centered care,
3 including patient navigation services.
- 4 (iii) Improvements to coordination of
5 transportation to health care facilities.
- 6 (iv) Development of provider networks
7 and other innovative models to engage phy-
8 sicians in voluntary efforts to serve the
9 medically underserved within a community.
- 10 (v) Recruitment, training, and com-
11 pensation of necessary personnel.
- 12 (vi) Coordinate the acquisition or
13 interconnected use of technology within a
14 community for the purpose of coordinating
15 care and improving provider communica-
16 tion, including implementation of shared
17 information systems or shared clinical sys-
18 tems to improve the quality of health care.
- 19 (vii) Development of common proc-
20 esses such as mechanisms for determining
21 eligibility for the programs provided
22 through the system, common identification
23 cards, sliding scale discounts, and moni-
24 toring and tracking of outcomes.

1 (viii) Development of specific preven-
2 tion and disease management tools and
3 processes.

4 (ix) Language access services.

5 (x) Facilitating the involvement of
6 community organizations to provide better
7 access to high-quality health care services
8 to individuals at risk for or who have
9 chronic diseases or cancer.

10 (xi) Helping patients overcome bar-
11 riers within the health care system to en-
12 sure prompt diagnostic and treatment res-
13 olution of an abnormal finding of cancer or
14 chronic disease.

15 (2) DIRECT PATIENT CARE LIMITATION.—Not
16 more than 20 percent of the funds provided under
17 a grant awarded under this section may be used for
18 providing direct patient care and services.

19 (3) RESERVATION OF FUNDS FOR NATIONAL
20 PROGRAM PURPOSES.—The Secretary may use not
21 more than 7 percent of funds appropriated to carry
22 out this section for providing technical assistance to
23 grantees, obtaining assistance of experts and con-
24 sultants, holding meetings, developing of tools, dis-
25 seminating of information, and evaluation.

1 (f) REPORTING BY GRANTEE.—A grantee under this
2 section shall report to the Secretary annually regarding—

3 (1) progress in meeting the goals and measur-
4 able objectives set forth in the grant application sub-
5 mitted by the grantee under subsection (b); and

6 (2) the extent to which activities conducted by
7 such grantee have—

8 (A) improved the effectiveness, efficiency,
9 and coordination of services for uninsured and
10 low-income individuals in the community served
11 by such grantee, using commonly accepted out-
12 come measures;

13 (B) resulted in the provision of better qual-
14 ity health care for individuals and families in
15 the community served; and

16 (C) resulted in the provision of health care
17 to such individuals at lower cost than would
18 have been possible in the absence of the activi-
19 ties conducted by such grantee.

20 (g) MAINTENANCE OF EFFORT.—With respect to ac-
21 tivities for which a grant under this section is authorized,
22 the Secretary may award such a grant only if the applicant
23 and each of the participating providers agree that the
24 grantee and each such provider will maintain its expendi-
25 tures of non-Federal funds for such activities at a level

1 that is not less than the level of such expenditures during
2 the fiscal year immediately preceding the fiscal year for
3 which the applicant is applying to receive such grant.

4 (h) TECHNICAL ASSISTANCE.—The Secretary may
5 provide any entity that receives a grant under this section
6 with technical and other nonfinancial assistance necessary
7 to meet the requirements of this section. The Secretary
8 may choose to provide such assistance by awarding a grant
9 to, or entering into a contract with, a State or national
10 not-for-profit organization with expertise in building suc-
11 cessful community coalitions.

12 (i) EVALUATION OF PROGRAM.—Not later than Sep-
13 tember 30, 2014, the Secretary shall prepare and submit
14 to the appropriate committees of Congress a report that
15 describes the extent to which projects funded under this
16 section have been successful in improving the effective-
17 ness, efficiency, and coordination of services in the com-
18 munities served by such projects, including whether the
19 projects resulted in the provision of better quality health
20 care for such individuals, and whether such care was pro-
21 vided at lower costs than would have been provided in the
22 absence of such projects.

23 (j) AUTHORIZATION OF APPROPRIATIONS.—There
24 are authorized to be appropriated to carry out this section

1 such sums as may be necessary for fiscal years 2010
2 through 2014.



Thurs 7/30
9:33 am
B

**AMENDMENT TO THE AMENDMENT IN THE
NATURE OF A SUBSTITUTE TO H.R. 3200
OFFERED BY MR. HILL OF INDIANA
(AINS-EC__001)**

[Inclusion of physician-owned entities:] Page 647,
lines 22 and 23, strike “IN HOSPITALS AND OTHER EN-
TITIES THAT BILL MEDICARE”.

Page 647, line 23, strike “Not later than” and in-
sert the following:

1 “(1) OWNERSHIP IN HOSPITALS AND OTHER
2 ENTITIES THAT BILL MEDICARE.—Not later than”.

Page 648, after line 7 insert the following:

3 “(2) ADDITIONAL PHYSICIAN OWNERSHIP.—In
4 addition to the requirement under paragraph (a)(1),
5 not later than March 31 of each year (beginning
6 with 2011) any applicable manufacturer, applicable
7 group purchasing organization, or applicable dis-
8 tributor shall submit to the Secretary, in such elec-
9 tronic form as the Secretary shall require, the fol-
10 lowing information regarding any ownership or in-
11 vestment interest (other than an ownership or in-
12 vestment interest in a publicly traded security and

1 mutual fund, as described in section 1877(c) held
2 by a physician (or an immediate family member of
3 such physician (as defined for purposes of section
4 1877(a))) in the applicable manufacturer, applicable
5 group purchasing organization or applicable dis-
6 tributor during the preceding year:

7 “(A) The dollar amount invested by each
8 physician holding such an ownership or invest-
9 ment interest.

10 “(B) The value and terms of each such
11 ownership or investment interest.

12 “(C) Any payment or other transfer of
13 value provided to a physician holding such an
14 ownership or investment interest (or to an enti-
15 ty or individual at the request of or designated
16 on behalf of a physician holding such an owner-
17 ship or investment interest), including the infor-
18 mation described in clauses (i) through (iii) of
19 paragraph (a)(1)(B), and information described
20 in subsection (f)(9)(A) and (f)(9)(B).

21 “(D) Any other information regarding the
22 ownership or investment interest the Secretary
23 determines appropriate.”

Page 651, line 18, page 652, lines 14 and 18, and page 653, line 15, after “manufacturer” insert “, applicable group purchasing organization, or applicable”.

Page 654, line 21, strike “; APPLICABLE DISTRIBUTOR”.

Page 654, line 24, strike “, and” and all that follows through page 655, line 2 and insert a period.

Page 656, amend lines 13 through 20 to read as follows:

1 “(5) APPLICABLE DISTRIBUTOR.—The term
2 ‘applicable distributor’ means an entity, other than
3 an applicable group purchasing organization, that
4 buys and resells, or receives a commission or other
5 similar form of payment, from another seller, for
6 selling or arranging for the sale of a covered drug,
7 device, biological, or medical supply.”.

Page 660, after line 2, insert the following:

8 “(10) APPLICABLE GROUP PURCHASING ORGA-
9 NIZATION.—The term ‘applicable group purchasing
10 organization’ means a group purchasing organiza-
11 tion (as defined by the Secretary) that purchases,
12 arranges for, or negotiates the purchase of a covered
13 drug, device, biological, or medical supply.”.

【Exemption for payments to providers who provide health care services to a manufacturer’s employees:】

Page 659, after line 20 insert the following:

1 “(ix) Payments made to a covered re-
2 cipient by an applicable manufacturer or
3 by a health plan affiliated with an applica-
4 ble manufacturer for medical care provided
5 to employees of such manufacturer and
6 their dependents.”.

**【Clarification that the definition of a “manufac-
turer” does not include the non-healthcare-related sub-
sidiaries or divisions of a manufacturer:】** Page 656, lines
18-19, strike “(or any subsidiary of or entity affiliated
with such entity)” and insert “or any entity under com-
mon ownership with such entity and which provides as-
sistance or support to such entity with respect to the pro-
duction, preparation, propagation, compounding, conver-
sion, processing, marketing, or distribution of a covered
drug, device, biological, or medical supply”.

Page 657, line 8, strike “(or any subsidiary of or en-
tity affiliated with such entity)” and insert “or any entity
under common ownership with such entity and which pro-
vides assistance or support to such entity with respect to
the production, preparation, propagation, compounding,

conversion, processing, marketing, or distribution of a covered drug, device, biological, or medical supply”.



AMENDMENT TO H.R.**OFFERED BY MR. MURPHY OF CONNECTICUT**

At the end of title V of division C, insert the following (and make such technical and conforming changes as may be appropriate):

1 Subtitle F—Women’s Health**2 SEC. 2551. OFFICE OF WOMEN’S HEALTH.**

3 (a) HEALTH AND HUMAN SERVICES OFFICE ON
4 WOMEN’S HEALTH.—

5 (1) ESTABLISHMENT.—Part A of title II of the
6 Public Health Service Act (42 U.S.C. 202 et seq.)
7 is amended by adding at the end the following:

8 **“SEC. 229. HEALTH AND HUMAN SERVICES OFFICE ON**
9 **WOMEN’S HEALTH.**

10 “(a) ESTABLISHMENT OF OFFICE.—There is estab-
11 lished within the Office of the Secretary, an Office on
12 Women’s Health (referred to in this section as the ‘Of-
13 fice’). The Office shall be headed by a Deputy Assistant
14 Secretary for Women’s Health who may report to the Sec-
15 retary.

16 “(b) DUTIES.—The Secretary, acting through the Of-
17 fice, with respect to the health concerns of women, shall—

1 “(1) establish short-range and long-range goals
2 and objectives within the Department of Health and
3 Human Services and, as relevant and appropriate,
4 coordinate with other appropriate offices on activi-
5 ties within the Department that relate to disease
6 prevention, health promotion, service delivery, re-
7 search, and public and health care professional edu-
8 cation, for issues of particular concern to women
9 throughout their lifespan;

10 “(2) provide expert advice and consultation to
11 the Secretary concerning scientific, legal, ethical,
12 and policy issues relating to women’s health;

13 “(3) monitor the Department of Health and
14 Human Services’ offices, agencies, and regional ac-
15 tivities regarding women’s health and identify needs
16 regarding the coordination of activities, including in-
17 tramural and extramural multidisciplinary activities;

18 “(4) establish a Department of Health and
19 Human Services Coordinating Committee on Wom-
20 en’s Health, which shall be chaired by the Deputy
21 Assistant Secretary for Women’s Health and com-
22 posed of senior level representatives from each of the
23 agencies and offices of the Department of Health
24 and Human Services;

1 “(5) establish a National Women’s Health In-
2 formation Center to—

3 “(A) facilitate the exchange of information
4 regarding matters relating to health informa-
5 tion, health promotion, preventive health serv-
6 ices, research advances, and education in the
7 appropriate use of health care;

8 “(B) facilitate access to such information;

9 “(C) assist in the analysis of issues and
10 problems relating to the matters described in
11 this paragraph; and

12 “(D) provide technical assistance with re-
13 spect to the exchange of information (including
14 facilitating the development of materials for
15 such technical assistance);

16 “(6) coordinate efforts to promote women’s
17 health programs and policies with the private sector;
18 and

19 “(7) through publications and any other means
20 appropriate, provide for the exchange of information
21 between the Office and recipients of grants, con-
22 tracts, and agreements under subsection (c), and be-
23 tween the Office and health professionals and the
24 general public.

1 “(c) GRANTS AND CONTRACTS REGARDING DU-
2 TIES.—

3 “(1) AUTHORITY.—In carrying out subsection
4 (b), the Secretary may make grants to, and enter
5 into cooperative agreements, contracts, and inter-
6 agency agreements with, public and private entities,
7 agencies, and organizations.

8 “(2) EVALUATION AND DISSEMINATION.—The
9 Secretary shall directly or through contracts with
10 public and private entities, agencies, and organiza-
11 tions, provide for evaluations of projects carried out
12 with financial assistance provided under paragraph
13 (1) and for the dissemination of information devel-
14 oped as a result of such projects.

15 “(d) REPORTS.—Not later than 1 year after the date
16 of enactment of this section, and every second year there-
17 after, the Secretary shall prepare and submit to the appro-
18 priate committees of Congress a report describing the ac-
19 tivities carried out under this section during the period
20 for which the report is being prepared.”.

21 “(2) TRANSFER OF FUNCTIONS.—There are
22 transferred to the Office on Women’s Health (estab-
23 lished under section 229 of the Public Health Serv-
24 ice Act, as added by this section), all functions exer-
25 cised by the Office on Women’s Health of the Public

1 Health Service prior to the date of enactment of this
2 section, including all personnel and compensation
3 authority, all delegation and assignment authority,
4 and all remaining appropriations. All orders, deter-
5 minations, rules, regulations, permits, agreements,
6 grants, contracts, certificates, licenses, registrations,
7 privileges, and other administrative actions that—

8 (A) have been issued, made, granted, or al-
9 lowed to become effective by the President, any
10 Federal agency or official thereof, or by a court
11 of competent jurisdiction, in the performance of
12 functions transferred under this paragraph; and

13 (B) are in effect at the time this section
14 takes effect, or were final before the date of en-
15 actment of this section and are to become effec-
16 tive on or after such date;

17 shall continue in effect according to their terms until
18 modified, terminated, superseded, set aside, or re-
19 voked in accordance with law by the President, the
20 Secretary, or other authorized official, a court of
21 competent jurisdiction, or by operation of law.

22 (b) CENTERS FOR DISEASE CONTROL AND PREVEN-
23 TION OFFICE OF WOMEN'S HEALTH.—Part A of title III
24 of the Public Health Service Act (42 U.S.C. 241 et seq.)
25 is amended by adding at the end the following:

1 **“SEC. 310A. CENTERS FOR DISEASE CONTROL AND PREVEN-**
2 **TION OFFICE OF WOMEN’S HEALTH.**

3 “(a) ESTABLISHMENT.—There is established within
4 the Office of the Director of the Centers for Disease Con-
5 trol and Prevention, an office to be known as the Office
6 of Women’s Health (referred to in this section as the ‘Of-
7 fice’). The Office shall be headed by a director who shall
8 be appointed by the Director of such Centers.

9 “(b) PURPOSE.—The Director of the Office shall—

10 “(1) report to the Director of the Centers for
11 Disease Control and Prevention on the current level
12 of the Centers’ activity regarding women’s health
13 conditions across, where appropriate, age, biological,
14 and sociocultural contexts, in all aspects of the Cen-
15 ters’ work, including prevention programs, public
16 and professional education, services, and treatment;

17 “(2) establish short-range and long-range goals
18 and objectives within the Centers for women’s health
19 and, as relevant and appropriate, coordinate with
20 other appropriate offices on activities within the
21 Centers that relate to prevention, research, edu-
22 cation and training, service delivery, and policy de-
23 velopment, for issues of particular concern to
24 women;

25 “(3) identify projects in women’s health that
26 should be conducted or supported by the Centers;

1 “(4) consult with health professionals, non-
2 governmental organizations, consumer organizations,
3 women’s health professionals, and other individuals
4 and groups, as appropriate, on the policy of the Cen-
5 ters with regard to women; and

6 “(5) serve as a member of the Department of
7 Health and Human Services Coordinating Com-
8 mittee on Women’s Health (established under sec-
9 tion 229(b)(4)).

10 “(c) DEFINITION.—As used in this section, the term
11 ‘women’s health conditions’, with respect to women of all
12 age, ethnic, and racial groups, means diseases, disorders,
13 and conditions—

14 “(1) unique to, significantly more serious for,
15 or significantly more prevalent in women; and

16 “(2) for which the factors of medical risk or
17 type of medical intervention are different for women,
18 or for which there is reasonable evidence that indi-
19 cates that such factors or types may be different for
20 women.”.

21 (c) OFFICE OF WOMEN’S HEALTH RESEARCH.—Sec-
22 tion 486(a) of the Public Health Service Act (42 U.S.C.
23 287d(a)) is amended by inserting “and who shall report
24 directly to the Director” before the period at the end
25 thereof.

1 (d) SUBSTANCE ABUSE AND MENTAL HEALTH
2 SERVICES ADMINISTRATION.—Section 501(f) of the Pub-
3 lic Health Service Act (42 U.S.C. 290aa(f)) is amended—

4 (1) in paragraph (1), by inserting “who shall
5 report directly to the Administrator” before the pe-
6 riod;

7 (2) by redesignating paragraph (4) as para-
8 graph (5); and

9 (3) by inserting after paragraph (3), the fol-
10 lowing:

11 “(4) OFFICE.—Nothing in this subsection shall
12 be construed to preclude the Secretary from estab-
13 lishing within the Substance Abuse and Mental
14 Health Administration an Office of Women’s
15 Health.”

16 (e) AGENCY FOR HEALTHCARE RESEARCH AND
17 QUALITY ACTIVITIES REGARDING WOMEN’S HEALTH.—
18 Part C of title IX of the Public Health Service Act (42
19 U.S.C. 299c et seq.) is amended—

20 (1) by redesignating sections 927 and 928 as
21 sections 928 and 929, respectively;

22 (2) by inserting after section 926 the following:

23 **“SEC. 927. ACTIVITIES REGARDING WOMEN’S HEALTH.**

24 **“(a) ESTABLISHMENT.—**There is established within
25 the Office of the Director, an Office of Women’s Health

1 and Gender-Based Research (referred to in this section
2 as the 'Office'). The Office shall be headed by a director
3 who shall be appointed by the Director of Healthcare and
4 Research Quality.

5 “(b) PURPOSE.—The official designated under sub-
6 section (a) shall—

7 “(1) report to the Director on the current
8 Agency level of activity regarding women’s health,
9 across, where appropriate, age, biological, and
10 sociocultural contexts, in all aspects of Agency work,
11 including the development of evidence reports and
12 clinical practice protocols and the conduct of re-
13 search into patient outcomes, delivery of health care
14 services, quality of care, and access to health care;

15 “(2) establish short-range and long-range goals
16 and objectives within the Agency for research impor-
17 tant to women’s health and, as relevant and appro-
18 priate, coordinate with other appropriate offices on
19 activities within the Agency that relate to health
20 services and medical effectiveness research, for
21 issues of particular concern to women;

22 “(3) identify projects in women’s health that
23 should be conducted or supported by the Agency;

24 “(4) consult with health professionals, non-
25 governmental organizations, consumer organizations,

1 women's health professionals, and other individuals
2 and groups, as appropriate, on Agency policy with
3 regard to women; and

4 “(5) serve as a member of the Department of
5 Health and Human Services Coordinating Com-
6 mittee on Women's Health (established under sec-
7 tion 229(b)(4)).”; and

8 (3) by adding at the end of section 928 (as re-
9 designated by paragraph (1)) the following:

10 “(e) WOMEN'S HEALTH.—For the purpose of car-
11 rying out section 927 regarding women's health, there are
12 authorized to be appropriated such sums as may be nec-
13 essary for each of the fiscal years 2010 through 2014.”.

14 (f) HEALTH RESOURCES AND SERVICES ADMINIS-
15 TRATION OFFICE OF WOMEN'S HEALTH.—Title VII of
16 the Social Security Act (42 U.S.C. 901 et seq.) is amended
17 by adding at the end the following:

18 **“SEC. 713. OFFICE OF WOMEN'S HEALTH.**

19 “(a) ESTABLISHMENT.—The Secretary shall estab-
20 lish within the Office of the Administrator of the Health
21 Resources and Services Administration, an office to be
22 known as the Office of Women's Health. The Office shall
23 be headed by a director who shall be appointed by the Ad-
24 ministrator.

25 “(b) PURPOSE.—The Director of the Office shall—

1 “(1) report to the Administrator on the current
2 Administration level of activity regarding women’s
3 health across, where appropriate, age, biological, and
4 sociocultural contexts;

5 “(2) establish short-range and long-range goals
6 and objectives within the Health Resources and
7 Services Administration for women’s health and, as
8 relevant and appropriate, coordinate with other ap-
9 propriate offices on activities within the Administra-
10 tion that relate to health care provider training,
11 health service delivery, research, and demonstration
12 projects, for issues of particular concern to women;

13 “(3) identify projects in women’s health that
14 should be conducted or supported by the bureaus of
15 the Administration;

16 “(4) consult with health professionals, non-
17 governmental organizations, consumer organizations,
18 women’s health professionals, and other individuals
19 and groups, as appropriate, on Administration policy
20 with regard to women; and

21 “(5) serve as a member of the Department of
22 Health and Human Services Coordinating Com-
23 mittee on Women’s Health (established under sec-
24 tion 229(b)(4) of the Public Health Service Act).

1 “(c) CONTINUED ADMINISTRATION OF EXISTING
2 PROGRAMS.—The Director of the Office shall assume the
3 authority for the development, implementation, adminis-
4 tration, and evaluation any projects carried out through
5 the Health Resources and Services Administration relat-
6 ing to women’s health on the date of enactment of this
7 section.

8 “(d) DEFINITIONS.—For purposes of this section:

9 “(1) ADMINISTRATION.—The term ‘Administra-
10 tion’ means the Health Resources and Services Ad-
11 ministration.

12 “(2) ADMINISTRATOR.—The term ‘Adminis-
13 trator’ means the Administrator of the Health Re-
14 sources and Services Administration.

15 “(3) OFFICE.—The term ‘Office’ means the Of-
16 fice of Women’s Health established under this sec-
17 tion in the Administration.”

18 (g) FOOD AND DRUG ADMINISTRATION OFFICE OF
19 WOMEN’S HEALTH.—Chapter IX of the Federal Food,
20 Drug, and Cosmetic Act (21 U.S.C. 391 et seq.) is amend-
21 ed by adding at the end the following:

22 **“SEC. 911. OFFICE OF WOMEN’S HEALTH.**

23 “(a) ESTABLISHMENT.—There is established within
24 the Office of the Commissioner, an office to be known as
25 the Office of Women’s Health (referred to in this section

1 as the 'Office'). The Office shall be headed by a director
2 who shall be appointed by the Commissioner of Food and
3 Drugs.

4 “(b) PURPOSE.—The Director of the Office shall—

5 “(1) report to the Commissioner of Food and
6 Drugs on current Food and Drug Administration
7 (referred to in this section as the 'Administration')
8 levels of activity regarding women's participation in
9 clinical trials and the analysis of data by sex in the
10 testing of drugs, medical devices, and biological
11 products across, where appropriate, age, biological,
12 and sociocultural contexts;

13 “(2) establish short-range and long-range goals
14 and objectives within the Administration for issues
15 of particular concern to women's health within the
16 jurisdiction of the Administration, including, where
17 relevant and appropriate, adequate inclusion of
18 women and analysis of data by sex in Administration
19 protocols and policies;

20 “(3) provide information to women and health
21 care providers on those areas in which differences
22 between men and women exist;

23 “(4) consult with pharmaceutical, biologics, and
24 device manufacturers, health professionals with ex-
25 pertise in women's issues, consumer organizations,

1 and women's health professionals on Administration
2 policy with regard to women;

3 “(5) make annual estimates of funds needed to
4 monitor clinical trials and analysis of data by sex in
5 accordance with needs that are identified; and

6 “(6) serve as a member of the Department of
7 Health and Human Services Coordinating Com-
8 mittee on Women's Health (established under sec-
9 tion 229(b)(4) of the Public Health Service Act).”.

10 (h) NO NEW REGULATORY AUTHORITY.—Nothing in
11 this section and the amendments made by this section may
12 be construed as establishing regulatory authority or modi-
13 fying any existing regulatory authority.

14 (i) LIMITATION ON TERMINATION.—Notwithstanding
15 any other provision of law, a Federal office of women's
16 health (including the Office of Research on Women's
17 Health of the National Institutes of Health) or Federal
18 appointive position with primary responsibility over wom-
19 en's health issues (including the Associate Administrator
20 for Women's Services under the Substance Abuse and
21 Mental Health Services Administration) that is in exist-
22 ence on the date of enactment of this section shall not
23 be terminated, reorganized, or have any of its powers or
24 duties transferred unless such termination, reorganization,

1 or transfer is approved by Congress through the adoption
2 of a concurrent resolution of approval.

3 (j) RULE OF CONSTRUCTION.—Nothing in this sec-
4 tion (or the amendments made by this section) shall be
5 construed to limit the authority of the Secretary of Health
6 and Human Services with respect to women's health, or
7 with respect to activities carried out through the Depart-
8 ment of Health and Human Services on the date of enact-
9 ment of this section.



Fri 7/31
9:22 am
C

**AMENDMENT TO THE AMENDMENT IN THE
NATURE OF A SUBSTITUTE TO H.R. 3200
OFFERED BY MR. Pallone**

At the end of title V of division C, add the following:

1 **Subtitle _____—Infant Mortality**
2 **Pilot Programs**

3 **SEC. ____ . INFANT MORTALITY PILOT PROGRAMS.**

4 (a) IN GENERAL.—The Secretary, acting through the
5 Director, shall award grants to eligible entities to create,
6 implement, and oversee infant mortality pilot programs.

7 (b) PERIOD OF A GRANT.—The period of a grant
8 under this section shall be 5 consecutive fiscal years.

9 (c) PREFERENCE.—In awarding grants under this
10 section, the Secretary shall give preference to eligible enti-
11 ties proposing to serve any of the 15 counties or groups
12 of counties with the highest rates of infant mortality in
13 the United States in the past 3 years.

14 (d) USE OF FUNDS.—Any infant mortality pilot pro-
15 gram funded under this section may—

16 (1) include the development of a plan that iden-
17 tifies the individual needs of each community to be
18 served and strategies to address those needs;

1 (2) provide outreach to at-risk mothers through
2 programs deemed appropriate by the Director;

3 (3) develop and implement standardized sys-
4 tems for improved access, utilization, and quality of
5 social, educational, and clinical services to promote
6 healthy pregnancies, full term births, and healthy in-
7 fancies delivered to women and their infants, such
8 as—

9 (A) counseling on infant care, feeding, and
10 parenting;

11 (B) postpartum care;

12 (C) prevention of premature delivery; and

13 (D) additional counseling for at-risk moth-
14 ers, including smoking cessation programs,
15 drug treatment programs, alcohol treatment
16 programs, nutrition and physical activity pro-
17 grams, postpartum depression and domestic vio-
18 lence programs, social and psychological serv-
19 ices, dental care, and parenting programs;

20 (4) establish a rural outreach program to pro-
21 vide care to at-risk mothers in rural areas;

22 (5) establish a regional public education cam-
23 paign, including a campaign to—

24 (A) prevent preterm births; and

1 (B) educate the public about infant mor-
2 tality; and

3 (6) provide for any other activities, programs,
4 or strategies as identified by the community plan.

5 (e) LIMITATION.—Of the funds received through a
6 grant under this section for a fiscal year, an eligible entity
7 shall not use more than 10 percent for program evalua-
8 tion.

9 (f) REPORTS ON PILOT PROGRAMS.—

10 (1) IN GENERAL.—Not later than 1 year after
11 receiving a grant, and annually thereafter for the
12 duration of the grant period, each entity that re-
13 ceives a grant under subsection (a) shall submit a
14 report to the Secretary detailing its infant mortality
15 pilot program.

16 (2) CONTENTS OF REPORT.—The reports re-
17 quired under paragraph (1) shall include informa-
18 tion such as the methodology of, and outcomes and
19 statistics from, the grantee's infant mortality pilot
20 program.

21 (3) EVALUATION.—The Secretary shall use the
22 reports required under paragraph (1) to evaluate,
23 and conduct statistical research on, infant mortality
24 pilot programs funded through this section.

1 **SEC. ____ . DEFINITIONS.**

2 For the purposes of this subtitle, the following defini-
3 tions apply:

4 (1) **SECRETARY.**—The term “Secretary” means
5 the Secretary of Health and Human Services.

6 (2) **DIRECTOR.**—The term “Director” means
7 the Director of the Centers for Disease Control and
8 Prevention.

9 (3) **ELIGIBLE ENTITY.**—The term “eligible enti-
10 ty” means a State, county, city, territorial, or tribal
11 health department that has submitted a proposal to
12 the Secretary that the Secretary deems likely to re-
13 duce infant mortality rates within the standard met-
14ropolitan statistical area involved.

15 (4) **TRIBAL.**—The term “tribal” refers to an
16 Indian tribe, a Tribal organization, or an Urban In-
17 dian organization, as such terms are defined in sec-
18 tion 4 of the Indian Health Care Improvement Act.

19 **SEC. ____ . AUTHORIZATION OF APPROPRIATIONS.**

20 To carry out this subtitle, there are authorized to be
21 appropriated \$10,000,000 for each of fiscal years 2010
22 through 2014.



Thurs 7/30
2:01 pm
A

**AMENDMENT TO THE AMENDMENT IN THE
NATURE OF A SUBSTITUTE TO H.R. 3200
OFFERED BY MR. PALLONE**

(AINS-EC_001)

In section 100(c) (relating to general definitions) re-designate paragraphs (14) through (25) as paragraphs (16) through (27), respectively.

In section 100(c), after paragraph 13, insert the following new paragraphs:

1 (14) INDIAN.—The term “Indian” has the
2 meaning given such term in section 4 of the Indian
3 Health Care Improvement Act (24 U.S.C. 1603).

4 (15) INDIAN HEALTH CARE PROVIDER.—The
5 term “Indian health care provider” means a health
6 care program operated by the Indian Health Service,
7 an Indian tribe, tribal organization, or urban Indian
8 organization as such terms are defined in section 4
9 of the Indian Health Care Improvement Act (25
10 U.S.C. 1603).

In section 204(b) (relating to standards for QHBP offering entities) redesignate paragraph (8) as paragraph (9).

In section 204(b), after paragraph (7), insert the following new paragraph:

1 (8) SPECIAL RULES WITH RESPECT TO INDIAN
2 ENROLLEES AND INDIAN HEALTH CARE PRO-
3 VIDERS.—

4 (A) CHOICE OF PROVIDERS.—The entity
5 shall—

6 (i) demonstrate to the satisfaction of
7 the Commissioner that it has contracted
8 with a sufficient number of Indian health
9 care providers to ensure timely access to
10 covered services furnished by such pro-
11 viders to individual Indians through the
12 entity's Exchange-participating health ben-
13 efits plan; and

14 (ii) agree to pay Indian health care
15 providers, whether such providers are par-
16 ticipating or nonparticipating providers
17 with respect to the entity, for covered serv-
18 ices provided to those enrollees who are eli-
19 gible to receive services from such pro-
20 viders at a rate that is not less than the
21 level and amount of payment which the en-
22 tity would make for the services of a par-

1 participating provider which is not an Indian
2 health care provider.

3 (B) SPECIAL RULE RELATING TO DIS-
4 CRIMINATION.—Provision of services by an In-
5 dian health care provider exclusively to Indians
6 and their dependents shall not constitute dis-
7 crimination under this Act.

 In section 204(e), add at the end the following new
paragraph:

8 (5) SPECIAL RULE RELATED TO COST-SHARING
9 AND INDIAN HEALTH CARE PROVIDERS.—The con-
10 tract under this section with a QHBP offering entity
11 for a health benefits plan shall provide that if an in-
12 dividual who is an Indian is enrolled in such a plan
13 and such individual receives a covered item or serv-
14 ice from an Indian health care provider (regardless
15 of whether such provider is in the plan's provider
16 network), the cost sharing for such item or service
17 shall be equal to the amount of cost-sharing that
18 would be imposed if such item or service—

19 (A) had been furnished by another pro-
20 vider in the plan's provider network; or

21 (B) in the case that the plan has no such
22 network, was furnished by a non-Indian pro-
23 vider.

In section 225 (relating to provider participation) strike subsection (b) and insert the following subsection:

1 (b) LICENSURE OR CERTIFICATION.—

2 (1) IN GENERAL.—Except as provided in para-
3 graph (2), the Secretary shall not allow a health
4 care provider to participate in the public health in-
5 surance option unless such provider is appropriately
6 licensed or certified under State law.

7 (2) SPECIAL RULE FOR IHS FACILITIES AND
8 PROVIDERS.—The requirements under paragraph
9 (1) shall not apply to—

10 (A) a facility that is operated by the In-
11 dian Health Service;

12 (B) a facility operated by an Indian Tribe
13 or tribal organization under the Indian Self De-
14 termination Act (Public Law 93-638);

15 (C) a health care professional employed by
16 the Indian Health Service; or

17 (D) A health care professional—

18 (i) who is employed to provide health
19 care services in a facility operated by an
20 Indian Tribe or tribal organization under
21 the Indian Self Determination Act; and

1 (ii) who is licensed or certified in any
2 State.



Fr: 7/31
11:19 am
A

AMENDMENT

OFFERED BY MR. ROSS OF ARKANSAS

Add at the end of subtitle F of title I of division A
the following new section:

1 **SEC. 156. STATE PROHIBITIONS ON DISCRIMINATION**
2 **AGAINST HEALTH CARE PROVIDERS.**

3 Notwithstanding any other provision of this Act (or
4 any amendment made by this Act), this Act (and any
5 amendment made by this Act) shall not supersede laws,
6 as they now or hereinafter exist, of any State or jurisdic-
7 tion designed to prohibit a health plan or insurer from
8 discriminating with respect to participation, reimburse-
9 ment, covered services, indemnification, or related require-
10 ments under a health plan or other health insurance cov-
11 erage against a health care provider who is acting within
12 the scope of that provider's license or certification under
13 applicable State law.



AMENDMENT

OFFERED BY MR. RUSH OF ILLINOIS

At the end of title V of division C, add the following:

- 1 **Subtitle _____—Secondary School**
2 **Health Sciences Training Program**
3 SEC. ____ . SECONDARY SCHOOL HEALTH SCIENCES TRAIN-
4 ING PROGRAM.
5 (a) PROGRAM.—The Secretary of Health and Human
6 Services, acting through the Administrator of the Health
7 Resources and Services Administration, and in consulta-
8 tion with the Secretary of Education, may establish a
9 health sciences training program consisting of awarding
10 grants and contracts under subsection (b) to prepare sec-
11 ondary school students for careers in health professions.
12 (b) DEVELOPMENT AND IMPLEMENTATION OF
13 HEALTH SCIENCES CURRICULA.—The Secretary may
14 make grants to, or enter into contracts with, eligible enti-
15 ties—
16 (1) to plan, develop, or implement secondary
17 school health sciences curricula, including curricula
18 in biology, chemistry, physiology, mathematics, nu-
19 trition, and other courses deemed appropriate by the
20 Secretary to prepare students for associate's or

1 bachelor's degree programs in health professions or
2 bachelor's degree programs in health professions-re-
3 lated majors; and
4 (2) to increase the interest of secondary school
5 students in applying to, and enrolling in, accredited
6 associate's or bachelor's degree programs in health
7 professions or bachelor's degree programs in health
8 professions-related majors, including through—
9 (A) work-study programs;
10 (B) programs to increase awareness of ca-
11 reers in health professions; and
12 (C) other activities to increase such inter-
13 est.
14 (c) ELIGIBILITY.—To be eligible for a grant or con-
15 tract under subsection (b), an entity shall—
16 (1) be a local educational agency; and
17 (2) provide assurances that activities under the
18 grant or contract will be carried out in partnership
19 with an accredited health professions school or pro-
20 gram, public or nonprofit private hospital, or public
21 or private nonprofit entity.
22 (d) PREFERENCE.—In awarding grants and con-
23 tracts under subsection (b), the Secretary shall give pref-
24 erence to entities that have a demonstrated record of the
25 following:

- 1 (1) Graduating the greatest percentage, or sig-
2 nificantly improving the percentage, of students who
3 have exhibited mastery in secondary school State
4 science standards.
- 5 (2) Graduating students of minority or dis-
6 advantaged backgrounds who are underrepresented
7 in—
- 8 (A) associate's or bachelor's degree pro-
9 grams in health professions or bachelor's degree
10 programs in health professions-related majors;
11 or
12 (B) health professions.
- 13 (e) REPORT.—The Secretary shall submit to the Con-
14 gress an annual report on the program carried out under
15 this section.
- 16 (f) DEFINITIONS.—In this section:
- 17 (1) The term “health profession” means the
18 profession of any member of the health workforce,
19 as defined in section 764(i) of the Public Health
20 Service Act, as added by section 2261.
- 21 (2) The term “local educational agency” has
22 the meaning given to the term in section 9101 of the
23 Elementary and Secondary Education Act of 1965
24 (20 U.S.C. 7801).
- 25 (3) The term “secondary school”—

1 (A) means a secondary school, as defined
2 in section 9101 of the Elementary and Sec-
3 ondary Education Act of 1965 (20 U.S.C.
4 7801); and
5 (B) includes any such school that is a mid-
6 dle school.

7 (g) AUTHORIZATION OF APPROPRIATIONS.—To carry
8 out this section, there are authorized to be appropriated
9 such sums as may be necessary for each of fiscal years
10 2010 through 2014.



1 **“Subpart XI—Collaborative Care Network Program**

2 **“SEC. 340H. COLLABORATIVE CARE NETWORK PROGRAM.**

3 “(a) IN GENERAL.—The Secretary may award grants
4 to eligible entities for the purpose of establishing model
5 projects to accomplish the following goals:

6 “(1) To reduce unnecessary use of items and
7 services furnished in emergency departments of hos-
8 pitals (especially to ensure that individuals without
9 health insurance coverage or with inadequate health
10 insurance coverage do not use the services of such
11 department instead of the services of a primary care
12 physician) through methods such as—

13 “(A) screening individuals who seek emer-
14 gency department services for possible eligibility
15 under relevant governmental health programs
16 or for subsidies under such programs; and

17 “(B) providing such individuals with refer-
18 rals for follow-up care and chronic condition
19 care.

20 “(2) To manage chronic conditions to reduce
21 their severity, negative health outcomes, and ex-
22 pense.

23 “(3) To encourage health care providers to co-
24 ordinate their efforts so that the most vulnerable pa-
25 tient populations seek and obtain primary care.

1 “(4) To provide more comprehensive and co-
2 ordinated care to vulnerable low income individuals
3 and individuals without health insurance coverage or
4 with inadequate coverage.

5 “(5) To provide mechanisms for improving both
6 quality and efficiency of care for low-in come individ-
7 uals and families, with an emphasis on those most
8 likely to remain uninsured despite the existence of
9 government programs to make health insurance
10 more affordable.

11 “(6) To increase preventive services, including
12 screening and counseling, to those who would other-
13 wise not receive such screening, in order to improve
14 health status and reduce long term complications
15 and costs.

16 “(7) To ensure the availability of community-
17 wide safety net services, including emergency and
18 trauma care.

19 “(b) ELIGIBILITY AND PARTICIPANT SELECTION.—

20 “(1) ELIGIBLE PROGRAM PARTICIPANT.—For
21 purposes of this section, the term ‘eligible program
22 participant’ means a safety net hospital that pro-
23 vides services to a high volume of low-income pa-
24 tients, as determined by the Secretary, and that is
25 to be a member of a collaborative care network de-

1 scribed in subsection (d) and selected by the Sec-
2 retary under paragraph (3) of this subsection.

3 “(2) APPLICATION.—An eligible program par-
4 ticipant representing a collaborative care network
5 described in subsection (d) shall submit to the Sec-
6 retary an application in such form and manner and
7 containing such information as specified by the Sec-
8 retary. Such information shall at least—

9 “(A) identify the health care providers par-
10 ticipating in the collaborative care network pro-
11 posed by the applicant and in the case a Feder-
12 ally qualified health center is not included as
13 such a participant, the reason such a center is
14 not so included;

15 “(B) include a description of how the pro-
16 viders plan to collaborate to provide comprehen-
17 sive and integrated care for low-income individ-
18 uals, including uninsured and underinsured in-
19 dividuals;

20 “(C) include a description of the organiza-
21 tional and joint governance structure of the col-
22 laborative care network in a manner so that it
23 is clear how decisions will be made;

24 “(D) define the geographic areas and pop-
25 ulations that the network intends to serve;

1 “(E) define the scope of services that the
2 network intends to provide and identify any
3 reasons why such services would not include a
4 suggested core service identified by the Sec-
5 retary under paragraph (4);

6 “(F) demonstrate the network’s ability to
7 meet the requirements of this section; and

8 “(G) provide assurances that (and include
9 a plan demonstrating how) grant funds received
10 by an eligible program participant shall be ap-
11 propriately distributed among all health care
12 providers participating in the collaborative care
13 network.

14 “(3) SELECTION OF PARTICIPANTS.—

15 “(A) IN GENERAL.—The Secretary shall
16 select eligible program participants to receive
17 grants from applications submitted under para-
18 graph (2) on the basis of quality of the proposal
19 involved, geographic diversity (including dif-
20 ferent States and regions served and urban and
21 rural diversity), and the number of low-income
22 and uninsured individuals that the proposal in-
23 tends to serve.

24 “(B) PRIORITY.—The Secretary shall give
25 priority to proposals from eligible program par-

1 participants that serve a high volume of low-income
2 individuals.

3 “(C) RENEWAL.—In subsequent years, the
4 Secretary may provide renewal grants to prior
5 year grant recipients.

6 “(4) SUGGESTED CORE SERVICES.—For pur-
7 poses of paragraph (2)(E), the Secretary shall de-
8 velop a list of suggested core services to be provided
9 by a collaborative care network. The Secretary may
10 select an eligible program participant under para-
11 graph (3), the application of which does not include
12 all such services, if such application provides a rea-
13 sonable explanation why such services are not pro-
14 posed to be included, and the Secretary determines
15 that the application is otherwise high quality.

16 “(5) TERMINATION AUTHORITY.—The Sec-
17 retary may terminate selection of a collaborative
18 care network under this section for good cause. Such
19 good cause shall include a determination that the
20 network has failed—

21 “(A) has failed to provide a comprehensive
22 range of coordinated and integrated health care
23 services as required under subsection (d)(3);

24 “(B) had failed to meet reasonable quality
25 standards;

1 “(C) has misappropriated funds provided
2 under this section; or

3 “(D) has failed to make progress toward
4 accomplishing goals set out in subsection (a).

5 “(c) USE OF GRANT FUNDS.—Grant funds provided
6 under the collaborative care network program shall be
7 available to an eligible program participant (or consortium
8 of participants) to create and support collaborative care
9 networks (described in subsection (d)) that would carry
10 out the following activities:

11 “(1) Assist low-income individuals without ade-
12 quate health care coverage to—

13 “(A) access and appropriately use health
14 services;

15 “(B) enroll in applicable public or private
16 health insurance programs;

17 “(C) obtain referrals to and see a primary
18 care provider in case such an individual does
19 not have a primary care provider; and

20 “(D) obtain appropriate care for chronic
21 conditions.

22 “(2) Improve health care by providing case man-
23 agement, application assistance, and appropriate re-
24 ferrals such as through methods to—

1 “(A) create and meaningfully use a health
2 information network to track patients across
3 collaborative providers;

4 “(B) perform health outreach, such as by
5 using neighborhood health workers who may in-
6 form individuals about the availability of safety
7 net and primary care available through the col-
8 laborative care network;

9 “(C) provide for follow-up outreach to re-
10 mind patients of appointments or follow-up care
11 instructions;

12 “(D) provide transportation to individuals
13 to and from the site of care;

14 “(E) expand the capacity to provide care
15 at any provider participating in the collabo-
16 rative care network, including through hiring
17 new staff, opening new clinics or other provider
18 sites after-hours, on weekends, or otherwise
19 providing an urgent care alternative to an
20 emergency department; and

21 “(F) provide a primary care provider or
22 medical home for each network patient.

23 “(d) COLLABORATIVE CARE NETWORKS.—

24 “(1) IN GENERAL.—

1 “(A) DESCRIPTION.—A collaborative care
2 network described in this subsection is a con-
3 sortium of health care providers with a joint
4 governance structure that provides a com-
5 prehensive range of coordinated and integrated
6 health care services for low-income patient pop-
7 ulations or medically underserved communities
8 (whether or not such individuals receive benefits
9 under title XVIII, XIX, or XXI of the Social
10 Security Act, private or other health insurance
11 or are uninsured or underinsured) that complies
12 with any applicable minimum eligibility require-
13 ments that the Secretary may determine appro-
14 priate.

15 “(B) REQUIRED INCLUSION.—Each such
16 network shall include

17 “(i) at least one eligible program par-
18 ticipant; and

19 “(ii) at least one Federally qualified
20 health center (as defined in section
21 1905(1)(2)(B) of such Act), unless no such
22 a center serves the geographic area pro-
23 posed to be served by the network, a center
24 exists but refuses to participate, or a cen-

1 ter places unreasonable conditions on such
2 participation.

3 “(C) ADDITIONAL INCLUSIONS.—Each
4 such network may include any of the following
5 additional providers:

6 “(i) A hospital.

7 “(ii) A county or municipal depart-
8 ment of health.

9 “(iii) A rural health clinic.

10 “(iv) A community clinic, including a
11 mental health clinic, substance abuse clin-
12 ic, or a reproductive health clinic.

13 “(v) A private practice physician or
14 group practice.

15 “(vi) A nurse or physician assistant or
16 group practice.

17 “(vii) An adult day care center.

18 “(viii) A home health provider.

19 “(ix) Any other type of provider speci-
20 fied by the Secretary, which has a desire to
21 serve low-income and uninsured patients.

22 “(D) CONSTRUCTION.—Nothing in this
23 section shall prohibit a single entity from quali-
24 fying as collaborative care network so long as
25 such single entity meets the criteria of a col-

1 laborative care network. If the network does not
2 include at least one Federally qualified health
3 center (as defined in section 1905(l)(2)(B) of
4 the Social Security Act), the application must
5 explain the reason pursuant to subsection
6 (b)(2)(A).

7 “(2) COMPREHENSIVE RANGE OF COORDINATED
8 AND INTEGRATED HEALTH CARE SERVICES.—The
9 Secretary may define criteria for evaluating the serv-
10 ices offered by a collaborative care network. Such
11 criteria may include the following:

12 “(A) Requiring collaborative care networks
13 to include at least the suggested core services
14 identified under subsection (b)(4), or whichever
15 subset of the suggested core services is applica-
16 ble to a particular network.

17 “(B) Requiring such networks to assign
18 each patient of the network to a primary care
19 provider responsible for managing that
20 patient”s care.

21 “(C) Requiring the services provided by a
22 collaborative care network to include support
23 services appropriate to meet the health needs of
24 low-income populations in the network”s com-
25 munity, which may include chronic care man-

1 agement, nutritional counseling, transportation,
2 language services, enrollment counselors, social
3 services and other services as proposed by the
4 network.

5 “(D) Providing that the services provided
6 by a collaborative care network may also in-
7 clude long term care services and other services
8 not specified in this subsection.

9 “(E) Providing for the approval by the
10 Secretary of a scope of collaborative care net-
11 work services for each network that addresses
12 an appropriate minimum scope of work con-
13 sistent with the setting of the network and the
14 health professionals available in the community
15 the network serves.

16 “(3) CLARIFICATION.—Participation in a col-
17 laborative care network shall not disqualify a health
18 care provider from reimbursement under title XVIII,
19 XIX, or XXI of the Social Security Act with respect
20 to services otherwise reimbursable under such title.
21 Nothing in this section shall prevent a collaborative
22 care network that is otherwise eligible to contract
23 with Medicare, a private health insurer, or any other
24 appropriate entity to provide care under Medicare,

1 under health insurance coverage offered by the in-
2 surer, or otherwise.

3 “(e) EVALUATIONS.—

4 “(1) PARTICIPANT REPORTS.—Beginning in the
5 third year following an initial grant, each eligible
6 program participant shall submit to the Secretary,
7 with respect to each year the participant has re-
8 ceived a grant, an evaluation on the activities carried
9 out by the collaborative care network of such partici-
10 pant under the collaborative care network program
11 and shall include—

12 “(A) the number of people served;

13 “(B) the most common health problems
14 treated;

15 “(C) any reductions in emergency depart-
16 ment use;

17 “(D) an accounting of how amounts re-
18 ceived were used; and

19 “(E) to the extent requested by the Sec-
20 retary, any quality measures or any other meas-
21 ures specified by the Secretary.

22 “(2) PROGRAM REPORTS.—The Secretary shall
23 submit to Congress an annual evaluation (beginning
24 not later than 6 months after the first reports under
25 paragraph (1) are submitted) on the extent to which

1 emergency department use was reduced as a result
2 of the activities carried out by the participant under
3 the program. Each such evaluation shall also include
4 information on—

5 “(A) the prevalence of certain chronic con-
6 ditions in various populations, including a com-
7 parison of such prevalence in the general popu-
8 lation versus in the population of individuals
9 with inadequate health insurance coverage;

10 “(B) demographic characteristics of the
11 population of uninsured and underinsured indi-
12 viduals served by the collaborative care network
13 involved; and

14 “(C) the conditions of such individuals for
15 whom services were requested at such emer-
16 gency departments of participating hospitals.

17 “(3) AUDIT AUTHORITY.—The Secretary may
18 conduct periodic audits and request periodic spend-
19 ing reports of participants under the collaborative
20 care network program.

21 “(f) CLARIFICATION.—Nothing in this section re-
22 quires a provider to report individually identifiable infor-
23 mation of an individual to government agencies unless the
24 individual consents, consistent with HIPAA privacy and
25 security law, as defined in section 3009(a)(2).

1 “(g) AUTHORIZATION OF APPROPRIATIONS.—There
2 are authorized to be appropriated to carry out this section
3 such sums as may be necessary for each of fiscal years
4 2010 through 2015.”.





Thurs 7/30
11:06 am
B

**AMENDMENT TO THE AMENDMENT IN THE
NATURE OF A SUBSTITUTE TO H.R. 3200
OFFERED BY MR. SARBANES OF MARYLAND AND
MR. DINGELL OF MICHIGAN**

(AINS-EC_001)

Add at the end of subtitle C of title VII of division
B the following:

1 SEC. 1726. FQHC COVERAGE.

2 Section 1905(l)(2)(B) of the Social Security Act (42
3 U.S.C. 1396d(l)(2)(B)) is amended—

4 (1) by striking “or” at the end of clause (iii);

5 (2) by striking the semicolon at the end of
6 clause (iv) and inserting “, and”; and

7 (3) by inserting after clause (iv) the following
8 new clause:

9 “(v) is receiving a grant under section 399Z-1
10 of the Public Health Service Act;”.



AMENDMENT

OFFERED BY MR. STUPAK OF MICHIGAN

Page 805, line 21, strike subparagraph (B) and insert the following:

1 (B) in paragraph (1), by striking “are not
2 subject to the requirements of this section” and
3 inserting “are subject to the requirements of
4 this section unless such drugs are subject to
5 discounts under section 340B of the Public
6 Health Service Act”.



Fr: 7/31

11:27 am

C

**AMENDMENT TO THE AMENDMENT IN THE
NATURE OF A SUBSTITUTE TO H.R. 3200
OFFERED BY MR. WAXMAN OF CALIFORNIA**

Amend the heading of subtitle A of title V of division C to read:

1 **Subtitle A—Drug Discount for**
2 **Rural and Other Hospitals; 340B**
3 **Program Integrity**

After the heading of subtitle A of title V of division C, insert the following:

4 **PART 1—DRUG DISCOUNT FOR RURAL AND**
5 **OTHER HOSPITALS**

At the end of subtitle A of title V of division C, add the following:

6 **PART 2—340B PROGRAM INTEGRITY**

7 **SEC. 2505. IMPROVEMENTS TO 340B PROGRAM INTEGRITY.**

8 (a) **INTEGRITY IMPROVEMENTS.**—Subsection (d) of
9 section 340B (42 U.S.C. 256b) is amended to read as follows:
10

11 “(d) **IMPROVEMENTS IN PROGRAM INTEGRITY.**—

12 “(1) **MANUFACTURER COMPLIANCE.**—

1 “(A) IN GENERAL.—From amounts appro-
2 priated under paragraph (4), the Secretary
3 shall provide for improvements in compliance by
4 manufacturers with the requirements of this
5 section in order to prevent overcharges and
6 other violations of the discounted pricing re-
7 quirements specified in this section.

8 “(B) IMPROVEMENTS.—The improvements
9 described in subparagraph (A) shall include the
10 following:

11 “(i) The establishment of a process to
12 enable the Secretary to verify the accuracy
13 of ceiling prices calculated by manufactur-
14 ers under subsection (a)(1) and charged to
15 covered entities, which shall include the
16 following:

17 “(I) Developing and publishing,
18 through an appropriate policy or regu-
19 latory issuance, standards and meth-
20 odology for the calculation of ceiling
21 prices under such subsection.

22 “(II) Comparing regularly the
23 ceiling prices calculated by the Sec-
24 retary with the quarterly pricing data

1 that is reported by manufacturers to
2 the Secretary.

3 “(III) Conducting periodic moni-
4 toring of sales transactions to covered
5 entities.

6 “(IV) Inquiring into any discrep-
7 ancies between ceiling prices and
8 manufacturer pricing data that may
9 be identified and taking, or requiring
10 manufacturers to take, corrective ac-
11 tion in response to such discrepancies.

12 “(ii) The establishment of procedures
13 for the issuance of refunds to covered enti-
14 ties by manufacturers in the event that the
15 Secretary finds there has been an over-
16 charge, including the following:

17 “(I) Submission to the Secretary
18 by manufacturers of an explanation of
19 why and how the overcharge occurred,
20 how the refunds will be calculated,
21 and to whom the refunds will be
22 issued.

23 “(II) Oversight by the Secretary
24 to ensure that the refunds are issued

1 accurately and within a reasonable pe-
2 riod of time.

3 “(iii) Notwithstanding any other pro-
4 vision of law prohibiting the disclosure of
5 ceiling prices or data used to calculate the
6 ceiling price, the provision of access to cov-
7 ered entities through an Internet website
8 of the Department of Health and Human
9 Services or contractor to the applicable
10 ceiling prices for covered drugs as cal-
11 culated and verified by the Secretary in a
12 manner that ensures protection of privi-
13 leged pricing data from unauthorized dis-
14 closure.

15 “(iv) The development of a mecha-
16 nism by which—

17 “(I) rebates, discounts, or other
18 price concessions provided by manu-
19 facturers to other purchasers subse-
20 quent to the sale of covered drugs to
21 covered entities are reported to the
22 Secretary; and

23 “(II) appropriate credits and re-
24 funds are issued to covered entities if
25 such rebates, discounts, or other price

1 concessions have the effect of lowering
2 the applicable ceiling price for the rel-
3 evant quarter for the drugs involved.

4 “(v) The selective auditing of manu-
5 facturers and wholesalers by the Secretary
6 or the Secretary’s contractor to ensure the
7 integrity of the drug discount program
8 under this section.

9 “(vi) The establishment of a require-
10 ment that manufacturers and wholesalers
11 use the identification system developed by
12 the Secretary for purposes of facilitating
13 the ordering, purchasing, and delivery of
14 covered drugs under this section, including
15 the processing of chargebacks for such
16 drugs.

17 “(vii) The imposition of sanctions in
18 the form of civil monetary penalties,
19 which—

20 “(I) shall be assessed according
21 to standards and procedures estab-
22 lished in regulations to be promul-
23 gated by the Secretary within one
24 year of the date of the enactment of

1 the America's Affordable Health
2 Choices Act of 2009;

3 “(II) shall not exceed \$5,000 for
4 each instance of overcharging a cov-
5 ered entity that may have occurred;
6 and

7 “(III) shall apply to any manu-
8 facturer with an agreement under this
9 section that knowingly charges a cov-
10 ered entity a price for purchase of a
11 drug that exceeds the maximum appli-
12 cable price under subsection (a)(1) or
13 that knowingly violates any other pro-
14 vision of this section.

15 “(2) COVERED ENTITY COMPLIANCE.—

16 “(A) IN GENERAL.—From amounts appro-
17 priated under paragraph (4), the Secretary
18 shall provide for improvements in compliance by
19 covered entities with the requirements of this
20 section in order to prevent diversion and viola-
21 tions of the duplicate discount provision and
22 other requirements under subsection (a)(5).

23 “(B) IMPROVEMENTS.—The improvements
24 described in subparagraph (A) shall include the
25 following:

1 “(i) The development of procedures to
2 enable and require covered entities to up-
3 date at least annually the information on
4 the Internet website of the Department of
5 Health and Human Services relating to
6 this section.

7 “(ii) The development of procedures
8 for the Secretary to verify the accuracy of
9 information regarding covered entities that
10 is listed on the website described in clause
11 (i).

12 “(iii) The development of more de-
13 tailed guidance describing methodologies
14 and options available to covered entities for
15 billing covered drugs to State Medicaid
16 agencies in a manner that avoids duplicate
17 discounts pursuant to subsection (a)(5)(A).

18 “(iv) The establishment of a single,
19 universal, and standardized identification
20 system by which each covered entity site
21 can be identified by manufacturers, dis-
22 tributors, covered entities, and the Sec-
23 retary for purposes of facilitating the or-
24 dering, purchasing, and delivery of covered

1 drugs under this section, including the
2 processing of chargebacks for such drugs.

3 “(v) The imposition of sanctions in
4 the form of civil monetary penalties,
5 which—

6 “(I) shall be assessed according
7 to standards and procedures estab-
8 lished in regulations promulgated by
9 the Secretary;

10 “(II) shall not exceed \$5,000 for
11 each violation; and

12 “(III) shall apply to any covered
13 entity that knowingly violates sub-
14 paragraph (a)(5)(B) or knowingly and
15 violates any other provision of this
16 section.

17 “(vi) The exclusion of a covered entity
18 from participation in the program under
19 this section, for a period of time to be de-
20 termined by the Secretary, in cases in
21 which the Secretary determines, in accord-
22 ance with standards and procedures estab-
23 lished in regulations, that—

1 “(I) a violation of a requirement
2 of this section was repeated and
3 knowing; and

4 “(II) imposition of a monetary
5 penalty would be insufficient to rea-
6 sonably ensure compliance.

7 “(vii) The referral of matters as ap-
8 propriate to the Food and Drug Adminis-
9 tration, the Office of Inspector General of
10 Department of Health and Human Serv-
11 ices, or other Federal agencies.

12 “(3) ADMINISTRATIVE DISPUTE RESOLUTION
13 PROCESS.—From amounts appropriated under para-
14 graph (4), the Secretary may establish and imple-
15 ment an administrative process for the resolution of
16 the following:

17 “(A) Claims by covered entities that manu-
18 facturers have violated the terms of their agree-
19 ment with the Secretary under subsection
20 (a)(1).

21 “(B) Claims by manufacturers that cov-
22 ered entities have violated subsection (a)(5)(A)
23 or (a)(5)(B).

24 “(4) AUTHORIZATION OF APPROPRIATIONS.—
25 There are authorized to be appropriated to carry out

1 this subsection, such sums as may be necessary for
2 fiscal year 2010 and each succeeding fiscal year.”.

3 (b) CONFORMING AMENDMENTS.—Section 340B(a)
4 (42 U.S.C. 256b(a)) is amended—

5 (1) by adding at the end of paragraph (1) the
6 following: “Such agreement shall require that the
7 manufacturer offer each covered entity covered
8 drugs for purchase at or below the applicable ceiling
9 price if such drug is made available to any other
10 purchaser at any price. Notwithstanding any other
11 provision of law, if the Secretary requests a manu-
12 facturer to enter into a new agreement that complies
13 with current law, the manufacturer will have the op-
14 tion of signing a new agreement or being determined
15 to not have entered into an agreement with the Sec-
16 retary that meets the requirements of this section.”;
17 and

18 (2) by adding at the end the following para-
19 graph:

20 “(11) QUARTERLY REPORTS.—An agreement
21 described in paragraph (1) shall require that the
22 manufacturer furnish the Secretary with reports on
23 a quarterly basis that include the following informa-
24 tion:

1 “(A) The price for each covered drug sub-
2 ject to the agreement that, according to the
3 manufacturer, represents the maximum price
4 that covered entities may permissibly be re-
5 quired to pay for the drug (referred to in this
6 section as the ‘ceiling price’).

7 “(B) The component information used to
8 calculate the ceiling price as determined nec-
9 essary to administer the requirements of the
10 program under this section.

11 “(C) Rebates, discounts, and other price
12 concessions provided by manufacturers to other
13 purchasers subsequent to the sale of covered
14 drugs to covered entities.”.



Thurs 7/30
8:37 pm
B
REV

AMENDMENT TO THE AMENDMENT IN THE
NATURE OF A SUBSTITUTE TO H.R. 3200
OFFERED BY MR. WELCH OF VERMONT
(AINS-EC_001)

Amend paragraph (2) of section 1128H(h) of the
Social Security Act, added by section 1451(a), to read as
follows:

1 “(2) NO PREEMPTION OF ADDITIONAL RE-
2 QUIREMENTS.—Paragraph (1) shall not preempt any
3 statute or regulation of a State or political subdivi-
4 sion of a State that requires any of the following:

5 “(A) The disclosure or reporting of infor-
6 mation not of the type required to be disclosed
7 or reported under this section.

8 “(B) The disclosure or reporting , in any
9 format, of information described in subsection
10 (f)(9)(C), except in the case of information de-
11 scribed in clause (i) of subsection (f)(9)(C).

12 “(C) The disclosure or reporting, ~~in any~~
13 ~~format, the type of information~~ by any person
14 or entity other than an applicable manufacturer
15 (as so defined) or a covered recipient (as de-
16 fined in subsection (f)).

- revised

1 “(D) The disclosure or reporting, in any
2 format, of the type of information required to
3 be disclosed or reported under this section to a
4 Federal, State, or local governmental agency for
5 public health surveillance, investigation, or
6 other public health purposes or health oversight
7 purposes.

8 Nothing in paragraph (1) shall be construed to limit
9 the discovery or admissibility of information de-
10 scribed in this paragraph in a criminal, civil, or ad-
11 ministrative proceeding.”.

