

111TH CONGRESS
1ST SESSION

H. R. 2400

To amend the Public Health Service Act to enhance efforts to address
antimicrobial resistance.

IN THE HOUSE OF REPRESENTATIVES

MAY 13, 2009

Mr. MATHESON introduced the following bill; which was referred to the
Committee on Energy and Commerce

A BILL

To amend the Public Health Service Act to enhance efforts
to address antimicrobial resistance.

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 “Strategies to Address
5 Antimicrobial Resistance Act”.

6 **SEC. 2. FINDINGS.**

7 The Congress finds as follows:

8 (1) The advent of the antibiotic era has saved
9 millions of lives and allowed for incredible medical
10 progress; however, the increased use and overuse of

1 antimicrobial drugs have correlated with increased
2 rates of antimicrobial resistance.

3 (2) Through mutation as well as other mecha-
4 nisms, bacteria and other infectious disease-causing
5 organisms—viruses, fungi, and parasites—develop
6 resistance to antimicrobial drugs over time. The
7 more antimicrobial drugs are used, whether appro-
8 priately or inappropriately, the more this contributes
9 to the development of antimicrobial resistance.

10 (3) The recent 2009 Influenza A: H1N1 virus
11 (also known as “Swine Flu Virus”) outbreak clearly
12 illustrates why infectious diseases experts are con-
13 cerned about drug resistance; although the H1N1
14 virus currently appears to be treatable by two class-
15 es of available antiviral drugs, it is resistant to other
16 classes, and should the virus mutate and become re-
17 sistant to all classes, which is possible, we would be
18 left extremely vulnerable.

19 (4) Scientific evidence suggests that the devel-
20 opment of antimicrobial resistance in humans is not
21 due only to use of antimicrobial drugs in humans,
22 but also may be caused by the use of antimicrobial
23 drugs in food-producing animals.

24 (5) A study estimates that in 2005 more than
25 94,000 invasive methicillin-resistant *Staphylococcus*

1 aureus (MRSA) infections occurred in the United
2 States and more than 18,500 of these infections re-
3 sulted in death—7 times more than a decade earlier.

4 (6) The recent 2009 Influenza A: H1N1 virus
5 outbreak exacerbates concerns about MRSA and
6 other bacteria that cause respiratory diseases given
7 that, during the 1918 influenza pandemic, many
8 thousands of deaths were caused by complications
9 due to secondary bacterial infections and not by the
10 influenza virus itself.

11 (7) Each year, nearly 2,000,000 people contract
12 bacterial infections in hospitals and approximately
13 90,000 of these people die from these infections.

14 (8) The current annual costs of antimicrobial-
15 resistant bacterial diseases are hard to quantify, but
16 a 1995 report by the Office of Technology Assess-
17 ment, an agency of Congress, which looked at 6 dif-
18 ferent antimicrobial-resistant strains of bacteria, cal-
19 culated that the minimum nationwide hospital costs
20 of just these strains of bacteria accounted for
21 \$1,300,000,000 annually in 1992 dollars
22 (\$1,870,000,000 in 2006 dollars).

23 (9) A 1998 Institute of Medicine report esti-
24 mated the societal cost of resistance as between
25 \$4,000,000,000 to \$5,000,000,000; many experts

1 argue the cost in 2009 may be close to 10 times
2 greater.

3 (10) The costs of antimicrobial-resistant infec-
4 tions in terms of lives lost and economically will only
5 rise as antimicrobial resistance continues to spread.

6 **SEC. 3. ANTIMICROBIAL RESISTANCE TASK FORCE.**

7 (a) IN GENERAL.—Section 319E of the Public
8 Health Service Act (42 U.S.C. 247d–5) is amended—

9 (1) in subsection (a)—

10 (A) in the subsection heading, by striking
11 “TASK FORCE” and inserting the following:
12 “ANTIMICROBIAL RESISTANCE OFFICE, TASK
13 FORCE, AND ADVISORY BOARD”;

14 (B) in paragraph (1)—

15 (i) by striking “as of the date of the
16 enactment of this section” and inserting
17 “as of September 30, 2006”; and

18 (ii) by adding at the end the fol-
19 lowing: “The Secretary shall, not later
20 than 1 year after the date of enactment of
21 the Strategies to Address Antimicrobial
22 Resistance Act, establish an Antimicrobial
23 Resistance Office in the Office of the Sec-
24 retary and appoint a director to that Of-
25 fice. The Secretary shall, not later than 1

1 year after the date of enactment of such
2 Act, establish the Public Health Anti-
3 microbial Advisory Board as an advisory
4 board to the Director of the Antimicrobial
5 Resistance Office. The Director of the
6 Antimicrobial Resistance Office shall serve
7 as the Director of the task force. To avoid
8 duplication and ensure that Federal re-
9 sources are used efficiently and effectively,
10 the Director shall work in conjunction with
11 the Federal agencies represented on the
12 Task Force to coordinate all antimicrobial
13 resistance activities undertaken and sup-
14 ported by the Federal Government, includ-
15 ing the activities and budgetary allocations
16 of the Office, task force, and Public Health
17 Antimicrobial Advisory Board.”;

18 (C) by amending paragraph (2) to read as
19 follows:

20 “(2) MEMBERS.—

21 “(A) MEMBERS OF THE ANTIMICROBIAL
22 RESISTANCE TASK FORCE.—The task force de-
23 scribed in paragraph (1) shall be composed of
24 representatives of such Federal agencies as the

1 Secretary determines necessary, including rep-
2 resentation of the following:

3 “(i) The Antimicrobial Resistance Of-
4 fice.

5 “(ii) The Assistant Secretary of Pre-
6 paredness and Response.

7 “(iii) The Centers for Disease Control
8 and Prevention.

9 “(iv) The Food and Drug Administra-
10 tion.

11 “(v) The National Institutes of
12 Health.

13 “(vi) The Agency for Healthcare Re-
14 search and Quality.

15 “(vii) The Centers for Medicare &
16 Medicaid Services.

17 “(viii) The Health Resources and
18 Services Administration.

19 “(ix) The Department of Agriculture.

20 “(x) The Department of Education.

21 “(xi) The Department of Defense.

22 “(xii) The Department of Veterans
23 Affairs.

24 “(xiii) The Environmental Protection
25 Agency.

1 “(xiv) The Department of Homeland
2 Security.

3 “(xv) The United States Agency for
4 International Development.

5 “(B) MEMBERS OF THE PUBLIC HEALTH
6 ANTIMICROBIAL ADVISORY BOARD.—

7 “(i) IN GENERAL.—The Public Health
8 Antimicrobial Advisory Board shall be
9 composed of 19 voting members, appointed
10 by the Secretary. Such members shall in-
11 clude experts from the medical professions
12 (including hospital and community-based
13 physicians), pharmacy, public health, vet-
14 erinary, research, and international health
15 communities, as well as one representative
16 from a public interest group.

17 “(ii) TERMS.—Each member ap-
18 pointed under clause (i) shall be appointed
19 for a term of 3 years, except that of the
20 19 members first appointed—

21 “(I) 6 shall be appointed for a
22 term of 12 months; and

23 “(II) 6 shall be appointed for a
24 term of 2 years.

1 “(iii) CHAIR.—The Secretary shall ap-
2 point a Chair of the Public Health Anti-
3 microbial Advisory Board from among its
4 members to lead and supervise the activi-
5 ties of the Advisory Board.

6 “(iv) DISCLOSURE OF FINANCIAL IN-
7 TERESTS.—Prior to a meeting of the Pub-
8 lic Health Antimicrobial Advisory Board,
9 each member of the Advisory Board shall
10 disclose to the Secretary any potential, rel-
11 evant financial interests as defined under
12 section 208(a) of title 18, United States
13 Code.”;

14 (D) in paragraph (3)(B), by striking “in
15 consultation with the task force described in
16 paragraph (1) and” and inserting “acting
17 through the Director of the Antimicrobial Re-
18 sistance Office and the Director of the Centers
19 for Disease Control and Prevention, and in con-
20 sultation with”; and

21 (E) by amending paragraph (4) to read as
22 follows:

23 “(4) MEETINGS AND DUTIES.—

24 “(A) ANTIMICROBIAL RESISTANCE OFFICE
25 RESISTANCE DUTIES.—The Director of the

1 Antimicrobial Resistance Office, working in
2 conjunction with the Federal agencies that are
3 represented on the task force described in para-
4 graph (1), shall issue an update to the Public
5 Health Action Plan to Combat Antimicrobial
6 Resistance within 18 months of the establish-
7 ment of the Office and biennial updates there-
8 after. The updates shall include enhanced plans
9 for addressing antimicrobial resistance in the
10 United States and internationally. The Director
11 of the Office shall post on a website these up-
12 dates as well as summaries of all non-propri-
13 etary data the Task Force makes available. The
14 Director of the Antimicrobial Resistance Office
15 shall work in conjunction with the Federal
16 agencies that are represented on the task force
17 described in paragraph (1), and in consultation
18 with the Public Health Antimicrobial Advisory
19 Board, to—

20 “(i) establish benchmarks for achiev-
21 ing the goals set forth in the action plan;

22 “(ii) assess the ongoing, observed pat-
23 terns of emergence of antimicrobial resist-
24 ance, and their impact on clinical outcomes

1 in terms of how patients feel, function, or
2 survive;

3 “(iii) assess how antimicrobial prod-
4 ucts are being used in humans, animals,
5 and plants, and the impact of such use in
6 furthering the development of resistance
7 and the implications thereof for patient
8 safety and public health;

9 “(iv) establish a priority list of human
10 infectious diseases with the greatest need
11 for development of new point-of-care and
12 other diagnostics, antimicrobial drugs, and
13 vaccines, and in particular serious and life-
14 threatening bacterial diseases, for which
15 there are few or no diagnostic or treatment
16 options;

17 “(v) recommend basic, clinical, epide-
18 miological, prevention, and translational
19 research where additional federally sup-
20 ported studies may be beneficial;

21 “(vi) recommend how to support anti-
22 microbial development through Food and
23 Drug Administration activities, including
24 through the agency’s Critical Path Initia-
25 tive;

1 “(vii) recommend how best to
2 strengthen and link antimicrobial resist-
3 ance-related surveillance and prevention
4 and control activities; and

5 “(viii) collaborate with the Assistant
6 Secretary for Preparedness and Response
7 to ensure that strategies to address anti-
8 microbial-resistance are coordinated with
9 initiatives aimed at pandemic influenza, in-
10 cluding the 2009 Influenza A: H1N1 virus
11 and H1N1 Avian Influenza virus, severe
12 acute respiratory syndrome, bioterrorism,
13 and other emerging health threats.

14 “(B) ANTIMICROBIAL RESISTANCE TASK
15 FORCE MEETINGS AND DUTIES.—

16 “(i) MEETINGS.—The Antimicrobial
17 Resistance Task Force shall convene peri-
18 odically as the Director of the Anti-
19 microbial Resistance Task Force deter-
20 mines to be appropriate, but not fewer
21 than twice a year, to consider issues relat-
22 ing to antimicrobial resistance.

23 “(ii) PUBLIC HEALTH ACTION
24 PLAN.—At least twice a year, the task
25 force described in paragraph (1) shall have

1 a meeting to review, discuss, and further
2 develop the Public Health Action Plan to
3 Combat Antimicrobial Resistance issued by
4 the interagency task force on antimicrobial
5 resistance in 2001. Among other issues,
6 the task force may discuss and review,
7 based on current need or concern—

8 “(I) antimicrobial clinical suscep-
9 tibility concentrations proposed, estab-
10 lished, or updated by the Food and
11 Drug Administration;

12 “(II) data obtained by govern-
13 ment agencies and, as possible, by pri-
14 vate sources on emerging anti-
15 microbial resistance related to clinical
16 outcomes in terms of how patients
17 function, feel, or survive as well as
18 data related to how antimicrobial
19 drugs may have been used inappropri-
20 ately;

21 “(III) surveillance data and pre-
22 vention and control activities regard-
23 ing emerging antimicrobial resistance
24 from reliable sources including the
25 Centers for Disease Control and Pre-

1 vention, the Food and Drug Adminis-
2 tration, the Department of Defense,
3 the Department of Veterans Affairs,
4 the Department of Agriculture, the
5 Environmental Protection Agency,
6 and as feasible from private sources
7 and international bodies;

8 “(IV) data on the amount of
9 antimicrobial products used in hu-
10 mans, animals, and plants from reli-
11 able sources including data from the
12 Centers for Disease Control and Pre-
13 vention, the Food and Drug Adminis-
14 tration, the Environmental Protection
15 Agency, the Department of Veterans
16 Affairs, the Centers for Medicare &
17 Medicaid Services, the Department of
18 Homeland Security, and the Depart-
19 ment of Agriculture, and as feasible
20 from private sources and international
21 bodies;

22 “(V) the impact of antimicrobial
23 resistance on human health resulting
24 from the approval of antimicrobial
25 drugs for use in humans or animals

1 (including consideration of and rec-
2 ommendations on potential manage-
3 ment plans to limit and reduce the
4 negative impacts of such resistance on
5 human health);

6 “(VI) reports of federally sup-
7 ported antimicrobial resistance re-
8 search and antimicrobial drug devel-
9 opment research activities (including
10 clinical, epidemiological, prevention,
11 and translational research) obtained
12 from Federal agencies, as well as re-
13 ports of research sponsored by other
14 countries, industry, and non-govern-
15 mental organizations;

16 “(VII) reports on efforts by the
17 Food and Drug Administration to de-
18 velop policies and guidances which en-
19 courage antimicrobial drug develop-
20 ment and appropriate use while main-
21 taining high standards for safety and
22 effectiveness;

23 “(VIII) health plan employer
24 data and information set (HEDIS)

1 measures pertaining to appropriate
2 use of antimicrobial drugs; and

3 “(IX) other data and issues the
4 task force described in paragraph (1)
5 identifies as relevant to the issue of
6 antimicrobial resistance.

7 “(iii) PENDING APPLICATIONS.—The
8 Food and Drug Administration may con-
9 sult with the Director of the Antimicrobial
10 Resistance Office concerning the pending
11 application of any antimicrobial drug appli-
12 cation submitted to the Secretary under
13 section 505 or 512 of the Federal Food,
14 Drug, and Cosmetic Act or the Public
15 Health Service Act.

16 “(C) PUBLIC HEALTH ANTIMICROBIAL AD-
17 VISORY BOARD MEETINGS AND DUTIES.—

18 “(i) MEETINGS.—The Public Health
19 Antimicrobial Advisory Board shall meet
20 as the Chair of the Public Health Anti-
21 microbial Advisory Board determines to be
22 appropriate, preferably in conjunction with
23 meetings of the Antimicrobial Resistance
24 Task Force, but not fewer than 2 times
25 each year.

1 “(ii) RECOMMENDATIONS.—The Pub-
2 lic Health Antimicrobial Advisory Board
3 shall make recommendations to the Sec-
4 retary, and the Antimicrobial Resistance
5 Office, regarding—

6 “(I) ways to encourage the avail-
7 ability of an adequate supply of safe
8 and effective antimicrobial products;

9 “(II) research priorities and
10 other measures (such as antimicrobial
11 drug resistance management plans) to
12 enhance the safety and efficacy of
13 antimicrobial products;

14 “(III) how best to implement and
15 update the goals of the Public Health
16 Action Plan to Combat Antimicrobial
17 Resistance;

18 “(IV) incentives necessary to es-
19 tablish uniform mechanisms and data
20 sets for State and local reporting of
21 resistance data;

22 “(V) the adequacy of existing
23 surveillance systems to collect anti-
24 microbial resistance data and how

1 best to improve the collection, report-
2 ing, and analysis of such data;

3 “(VI) the development of a na-
4 tional plan for the collection and anal-
5 ysis of isolates of resistant pathogens,
6 including establishing priorities as to
7 which isolates should be collected;

8 “(VII) the implementation and
9 evaluation of interventions to promote
10 appropriate antimicrobial drug use in
11 both inpatient and outpatient settings;
12 and

13 “(VIII) areas for government,
14 nongovernment, and international co-
15 operation to strengthen implementa-
16 tion of the Public Health Action Plan
17 to Combat Antimicrobial Resistance.

18 “(D) AVAILABILITY OF INFORMATION.—
19 The Antimicrobial Resistance Office shall en-
20 sure that all information shall be made avail-
21 able to the public on the website described in
22 subparagraph (A) consistent with section 8 of
23 the Strategies to Address Antimicrobial Resist-
24 ance Act.”;

1 (2) by amending subsection (b) to read as fol-
2 lows:

3 “(b) ANTIMICROBIAL RESISTANCE STRATEGIC RE-
4 SEARCH PLAN.—The Secretary, acting through the Direc-
5 tor of the Antimicrobial Resistance Office, the Director
6 of the Centers for Disease Control and Prevention, and
7 the Director of the National Institutes of Health, and in
8 consultation with other Federal agencies and the Public
9 Health Antimicrobial Advisory Board, shall develop an
10 antimicrobial resistance strategic research plan that
11 strengthens existing epidemiological, interventional, clin-
12 ical, behavioral, translational, and basic research efforts
13 to advance the understanding of—

14 “(1) the development, implementation, and effi-
15 cacy of interventions to prevent and control the
16 emergence and transmission of antimicrobial resist-
17 ance;

18 “(2) how best to optimize antimicrobial effec-
19 tiveness while limiting the emergence of resistance,
20 including addressing issues related to duration of
21 therapy, effectiveness of therapy in self-resolving dis-
22 eases, and determining populations most likely to
23 benefit from antimicrobial drugs;

24 “(3) the extent to which the use of anti-
25 microbial products in humans, animals, plants, and

1 other uses accelerates development and transmission
2 of antimicrobial resistance;

3 “(4) the natural histories of infectious diseases
4 (including defining the disease, diagnosis, severity,
5 and the time course of illness);

6 “(5) the development of new therapeutics, in-
7 cluding antimicrobial drugs, biologics, and devices
8 against resistant pathogens, and in particular dis-
9 eases for which few or no therapeutics are in devel-
10 opment;

11 “(6) the development and testing of medical
12 diagnostics to identify patients with infectious dis-
13 ease and identify the exact cause of infectious dis-
14 eases syndromes, particularly with respect to the de-
15 tection of pathogens resistant to antimicrobial drugs;

16 “(7) the epidemiology, pathogenesis, mecha-
17 nisms, and genetics of antimicrobial resistance; and

18 “(8) the sequencing of the genomes, or other
19 DNA analysis, or other comparative analysis of pri-
20 ority pathogens (as determined by the Public Health
21 Antimicrobial Advisory Board), in collaboration with
22 the Department of Defense and the Joint Genome
23 Institute of the Department of Energy.”;

24 (3) in subsection (c)—

1 (A) by inserting “acting through the Di-
2 rector of the Antimicrobial Resistance Office,”
3 after “The Secretary,”; and

4 (B) by striking “members of the task force
5 described in subsection (a),”;

6 (4) in subsection (d)(1), by inserting “, through
7 the Antimicrobial Resistance Office,” after “The
8 Secretary”; and

9 (5) in subsection (e)—

10 (A) in paragraph (1), by inserting “, act-
11 ing through the Director of the Antimicrobial
12 Resistance Office,” after “The Secretary”;

13 (B) in paragraph (3), by inserting “, act-
14 ing through the Antimicrobial Resistance Of-
15 fice,” after “The Secretary”; and

16 (C) by adding at the end the following:

17 “(4) PREFERENCE IN MAKING AWARDS.—In
18 making awards under paragraph (1), the Secretary
19 shall give preference to eligible entities that will use
20 grant funds to establish demonstration projects to
21 assess the scope of the antimicrobial resistance prob-
22 lem and the level of appropriate and inappropriate
23 use of antimicrobial drugs especially related to self-
24 resolving infections, including the validation of mod-
25 els that may lead to the development of quality

1 measures for health care providers prescribing anti-
2 microbial drugs.”.

3 (b) ENSURE ACCESS TO ANTIMICROBIAL DATA AND
4 RESEARCH.—The Director of the Antimicrobial Resist-
5 ance Office shall work with the agencies represented on
6 the Antimicrobial Resistance Task Force to identify rel-
7 evant data and formats, and mechanisms for commu-
8 nicating such data to the Antimicrobial Resistance Office
9 and Antimicrobial Resistance Task Force and, in a man-
10 ner consistent with section 8 of this Act, with the Public
11 Health Antimicrobial Advisory Board and the public, in-
12 cluding relevant data obtained by the agencies through
13 contracts with other organizations, including—

14 (1) use and clinical outcomes data on patients
15 receiving antimicrobial drugs for the treatment, pre-
16 vention, or diagnosis of infection or infectious dis-
17 eases;

18 (2) surveillance data regarding emerging anti-
19 microbial drug resistance;

20 (3) susceptibility data related to antimicrobial
21 drug use;

22 (4) data related to the amount of antimicrobial
23 products used in humans, animals, and plants;

24 (5) data from federally funded research in-
25 tended to support antimicrobial drug development;

1 (6) data demonstrating the impact of research,
2 surveillance, and prevention and control initiatives in
3 understanding and controlling antimicrobial resist-
4 ance; and

5 (7) data regarding implementation and evalua-
6 tion of interventions to improve antimicrobial drug
7 prescribing practices.

8 **SEC. 4. COLLECTION OF ANTIMICROBIAL DRUG DATA.**

9 (a) SUBMISSION OF HUMAN AND ANIMAL DRUG DIS-
10 TRIBUTION DATA.—Chapter V of the Federal Food, Drug,
11 and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by
12 inserting after section 512 the following:

13 **“SEC. 512A. SUBMISSION OF HUMAN AND ANIMAL DRUG**
14 **DISTRIBUTION DATA.**

15 “(a) IN GENERAL.—Notwithstanding any other pro-
16 vision of law, the Secretary shall require that each sponsor
17 of a human antimicrobial drug product which is approved
18 under section 505 (including section 505(j)) and sold or
19 distributed in the United States, submit antimicrobial
20 drug sales and distribution data. Such data shall be—

21 “(1) submitted not later than 60 days after the
22 beginning of the subsequent calendar year;

23 “(2) reported on the calendar year and seg-
24 regated by month;

1 “(3) in such format, and utilize any such unit
2 of measure, as the Secretary by regulation deems
3 necessary and appropriate to ensure the reported
4 data is comparable and reliable; and

5 “(4) made available to the Antimicrobial Resist-
6 ance Office and the Antimicrobial Resistance Task
7 Force.

8 “(b) CONFIDENTIALITY.—To protect proprietary
9 commercial information, officials who serve in the Anti-
10 microbial Resistance Office and on the Antimicrobial Re-
11 sistance Task Force shall sign a confidentiality agreement
12 prior to reviewing any such data to which access is granted
13 under subsection (a)(4).”.

14 (b) SUBMISSION OF ANIMAL SALES AND DISTRIBUTION DATA.—Section 512(l)(3) (21 U.S.C. 360b(l)(3)) is
15 amended—
16 amended—

17 (1) in subparagraph (C)—

18 (A) in clause (ii), by deleting “and” at the
19 end;

20 (B) in clause (iii), by striking the period at
21 the end and inserting “; and”; and

22 (C) by adding at the end the following:

23 “(iv) contain any such additional in-
24 formation, be in such format, and utilize
25 any such unit of measure as the Secretary

1 by regulation deems necessary and appro-
2 priate to ensure the reported data is com-
3 parable and reliable.”; and

4 (2) in subparagraph (D), by striking “may”
5 and inserting “shall”.

6 (c) DATA FROM ADDITIONAL SOURCES.—

7 (1) IN GENERAL.—The Secretary, acting
8 through the Director of the Antimicrobial Resistance
9 Office, shall explore opportunities to secure from pri-
10 vate vendors and health care organizations reliable
11 and comparable animal and human antimicrobial
12 drug consumption data (volume antimicrobial dis-
13 tribution data and antimicrobial use, including pre-
14 scription data) by State or metropolitan area, as
15 necessary, to supplement the antimicrobial drug con-
16 sumption data to be collected under this section for
17 the purpose of demonstrating how the consumption
18 of antimicrobial drugs for human and animal uses
19 may affect the development of resistance over time
20 and within geographic locations and to institute pre-
21 ventive interventions.

22 (2) NEGOTIATIONS.—The Director of the Anti-
23 microbial Resistance Office may enter into negotia-
24 tions with private vendors and health care organiza-
25 tions to determine acceptable scope and parameters

1 for summaries of antimicrobial drug consumption
2 data that is collected under this section publicly
3 available for research purposes.

4 (3) OTHER MEANS TO SECURE DATA.—If the
5 Director of the Antimicrobial Resistance Office is
6 not able to secure sufficient supplemental anti-
7 microbial drug consumption data for human and
8 animal uses through private vendors and health care
9 organizations as provided for in this section, the
10 Secretary shall consider other means to secure such
11 consumption data, including through the conduct of
12 surveys about how antimicrobial drugs are used in
13 various settings.

14 (d) COLLECTION OF ANTIMICROBIAL PRESCRIPTION
15 DATA.—

16 (1) CLINICAL OUTCOMES DATA.—The Director
17 of the Antimicrobial Resistance Office, the Under
18 Secretary for Health of the Department of Veterans
19 Affairs, and the Administrator of the Centers for
20 Medicare & Medicaid Services shall work together to
21 collect and analyze relevant drug utilization data
22 and clinical outcomes data, as determined relevant
23 by the Director of the Antimicrobial Resistance Of-
24 fice, on patients who receive services funded by such
25 agencies and who are receiving prescription anti-

1 microbial agents for the treatment or prevention of
2 infection or infectious diseases.

3 (2) ORGANIZATION.—Any data collected under
4 paragraph (1) shall be organized by—

5 (A) indication (including results of diag-
6 nostic studies when available);

7 (B) dosage;

8 (C) route of administration;

9 (D) duration;

10 (E) age of the patient; and

11 (F) geographic region.

12 (3) INTERVENTIONS AND ANALYSIS.—The
13 Under Secretary for Health of the Department of
14 Veterans Affairs, the Administrator of the Centers
15 for Medicare & Medicaid Services, and the Director
16 of the Antimicrobial Resistance Office shall work to-
17 gether to identify and report upon interventions that
18 prevent and control the development of antimicrobial
19 resistance and to include within such reports, where
20 appropriate, an analysis of the following—

21 (A) intra- and extra-label antimicrobial
22 use;

23 (B) where challenges to appropriate use re-
24 main;

1 (C) trends and variations in antimicrobial
2 resistance rates; and

3 (D) the relationship between drug use and
4 resistance.

5 (e) PUBLIC AVAILABILITY OF DATA.—The Director
6 of the Antimicrobial Resistance Office shall make sum-
7 maries of the data received under this section publicly
8 available and ensure that such summaries are updated and
9 published, in a manner consistent with section 8, at least
10 once annually on the website described in section
11 319E(a)(4)(A) of the Public Health Service Act (42
12 U.S.C. 247d–5(a)(4)(A)) in order to support epidemiologic
13 and microbiologic research.

14 **SEC. 5. ANTIMICROBIAL RESISTANCE SURVEILLANCE AND**
15 **RESEARCH NETWORK.**

16 (a) IN GENERAL.—The Secretary, through the Direc-
17 tor of the Centers for Disease Control and Prevention and
18 the Director of the National Institutes of Health, shall es-
19 tablish at least 10 Antimicrobial Resistance Surveillance
20 and Research Network sites to strengthen the national ca-
21 pacity to—

22 (1) describe and confirm regional outbreaks
23 through surveillance of locally available clinical
24 specimens;

1 (2) assess, integrate, and address local and na-
2 tional antimicrobial resistance patterns;

3 (3) facilitate research on prevention, control,
4 and treatment of resistant organisms; and

5 (4) serve as a clinical trials network for opti-
6 mizing antimicrobial drug effectiveness.

7 (b) GEOGRAPHIC DISTRIBUTION.—The sites estab-
8 lished under subsection (a) shall be geographically distrib-
9 uted across the United States.

10 (c) NONDUPLICATION OF CURRENT NATIONAL CA-
11 PACITY.—The sites established under subsection (a) may
12 be based in academic centers, health departments, and ex-
13 isting surveillance sites.

14 (d) RESPONSIBILITIES.—The Network of sites estab-
15 lished under subsection (a) shall—

16 (1) monitor the emergence and changes in the
17 patterns of antimicrobial resistant pathogens in indi-
18 viduals;

19 (2) study the molecular epidemiology of such
20 pathogens;

21 (3) evaluate the efficacy of new and existing
22 interventions to prevent or limit the emergence of
23 antimicrobial resistance throughout the geographic
24 region of the site;

1 (4) provide to the Centers for Disease Control
2 and Prevention isolates of resistant pathogens, and
3 in particular, pathogens that show new or atypical
4 patterns of resistance adversely affecting public
5 health;

6 (5) conduct clinical research to develop natural
7 histories of infectious disease and to study duration
8 of antimicrobial use related to resistance develop-
9 ment, among other things;

10 (6) assess the feasibility, cost-effectiveness, and
11 appropriateness of surveillance and screening pro-
12 grams in differing health care and institutional set-
13 tings, such as schools; and

14 (7) evaluate current treatment protocols and
15 make appropriate recommendations on best practices
16 for treating drug resistant infections.

17 (e) COORDINATION.—The sites established under
18 subsection (a) shall share data and cooperate with the
19 Centers for Disease Control and Prevention and the Na-
20 tional Institutes of Health.

21 (f) DATA ACCESS.—The Director of the Centers for
22 Disease Control and Prevention and the Director of the
23 National Institutes of Health shall ensure that summary
24 reports of data obtained by the Antimicrobial Resistance
25 Surveillance and Research Network sites are made avail-

1 able to the Antimicrobial Resistance Task Force and, in
 2 a manner consistent with section 8 of this Act, with the
 3 Public Health Antimicrobial Advisory Board and the pub-
 4 lic, for review on an ongoing basis .

5 **SEC. 6. SUPPLEMENT NOT SUPPLANT.**

6 Section 319E(f) of the Public Health Service Act (42
 7 U.S.C. 247d–5(f)) is amended to read as follows:

8 “(f) SUPPLEMENT NOT SUPPLANT.—Funds appro-
 9 priated under this section shall be used to supplement and
 10 not supplant other Federal, State, and local public funds
 11 provided for activities under this section, including funds
 12 appropriated for the Centers for Disease Control and Pre-
 13 vention and the National Institutes of Health.”.

14 **SEC. 7. AUTHORIZATION OF APPROPRIATIONS.**

15 Section 319E(g) of the Public Health Service Act (42
 16 U.S.C. 247d–5(g)) is amended to read as follows:

17 “(g) AUTHORIZATION OF APPROPRIATIONS.—

18 “(1) AUTHORIZATION.—There are authorized to
 19 be appropriated to carry out this section (other than
 20 subsection (b)) \$45,000,000 for fiscal year 2010,
 21 \$65,000,000 for fiscal year 2011, and \$120,000,000
 22 for fiscal years 2012 through 2014.

23 “(2) ALLOCATION.—Of the amount appro-
 24 priated to carry out this section for a fiscal year, not
 25 less than one-third of such amount shall be made

1 available for activities of the Centers for Disease
2 Control and Prevention under subsections (a)(3)(B)
3 and (c), of which an appropriate amount shall be al-
4 located to educational programs under subsection (c)
5 dedicated to the reduction of inappropriate anti-
6 microbial use.”.

7 **SEC. 8. PROTECTION OF CONFIDENTIAL AND NATIONAL SE-**
8 **CURITY INFORMATION.**

9 Except as otherwise required by law, this Act (and
10 the amendments made by this Act) shall not permit public
11 disclosure of trade secrets, confidential commercial infor-
12 mation, or material inconsistent with national security
13 that is obtained by any person under this Act.

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