

108TH CONGRESS
1ST SESSION

H. R. 2196

To improve the quality, availability, diversity, personal privacy, and innovation of health care in the United States.

IN THE HOUSE OF REPRESENTATIVES

MAY 21, 2003

Mr. ROHRABACHER introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committees on Government Reform, and Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To improve the quality, availability, diversity, personal privacy, and innovation of health care in the United States.

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; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Medical Independence, Privacy, and Innovation Act of
6 2003”.

7 (b) TABLE OF CONTENTS.—The table of contents of
8 this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—TAX-RELATED PROVISIONS

- Sec. 101. Findings.
- Sec. 102. Deduction of medical expenses for individuals.
- Sec. 103. Medical checking accounts.
- Sec. 104. Decrease in minimum annual deductibles under a high deductible health plan for purposes of Archer MSAs.

TITLE II—MEDICAL PRIVACY

- Sec. 201. Findings.
- Sec. 202. Modification of regulations on privacy of individually identifiable health information.
- Sec. 203. Restrictions on the use of the social security account number.
- Sec. 204. Prohibition of governmentwide uniform identifying numbers.
- Sec. 205. Prohibition of government-established identifiers.

TITLE III—MODIFICATIONS REGARDING REGULATION OF DRUGS
UNDER FEDERAL FOOD, DRUG, AND COSMETIC ACT

- Sec. 301. Definition of drug.
- Sec. 302. Striking of effectiveness requirement; modifications regarding patent listings, patent certifications, and thirty-month rule.
- Sec. 303. Importation of certain drugs.

1 **TITLE I—TAX-RELATED**
2 **PROVISIONS**

3 **SEC. 101. FINDINGS.**

4 The Congress finds the following:

5 (1) Current law confers tax benefits for health
6 insurance provided as an employee fringe benefit,
7 but no similar tax benefit for health insurance pur-
8 chased by individuals thus creating an unfair bias
9 toward employer provided medical insurance plans
10 and an unfair discrimination against individuals who
11 seek marketplace alternatives to health insurance.

12 (2) Current law confers a tax benefits for third
13 party payment of medical expenses but no similar
14 tax benefits for direct individual payment of medical
15 expenses. This has promoted employer-provided

1 third party payment systems and discouraged direct
2 doctor-patient relationships.

3 (3) The current tax treatment of medical ex-
4 penses has resulted in a greatly distorted market-
5 place in medical insurance where decreased opportu-
6 nities for private personal health insurance has re-
7 duced competition both for medical insurance and
8 health care services. This has resulted in an in-
9 creased cost of both health insurance and health
10 care services and fostered overuse of low high pre-
11 mium health insurance plans.

12 (4) The current tax treatment of medical ex-
13 penses has restricted the freedom of individuals to
14 exercise direct control over their health care dollars.
15 The exclusion from gross income for employer-pro-
16 vided health care with no corresponding tax benefit
17 for health insurance and health care costs borne by
18 individuals represents a strong incentive toward em-
19 ployers group plans.

20 (5) The tax codes preferment of employer-pro-
21 vided group plans has triggered a marketplace re-
22 sponse reflected in the significant increases in large
23 health care delivery, and the creation of a relative
24 few health care conglomerates in lieu of thousands
25 of competitive providers of medical insurance and

1 services. This has increasingly placed medical deci-
2 sions in the hands of health care bureaucracies and
3 has eroded doctor-patient relationships.

4 (6) The role of the marketplace in both medical
5 insurance and medical services should be strength-
6 ened. The discriminatory tax policies in the area of
7 health insurance and health care should be ended.
8 Private individuals should be able to contract for
9 their health insurance and health care delivery in an
10 atmosphere free of discriminatory tax pressures.
11 High deductible low premium as well as catastrophic
12 alternatives in health insurance should be viable op-
13 tions for all Americans.

14 (7) Consumers should have the freedom to pur-
15 chase the health insurance types of their own choice,
16 to choose their own doctors and to make their own
17 decisions about their health care. Elimination of the
18 discriminatory tax codes regarding health choices
19 will encourage greater choice and competition, there-
20 by reducing the cost of necessary insurance for all
21 Americans. This will enable millions more Americans
22 to obtain needed health coverage.

1 **SEC. 102. DEDUCTION OF MEDICAL EXPENSES FOR INDIVIDUALS.**
2

3 (a) IN GENERAL.—Subsection (a) of section 213 of
4 the Internal Revenue Code of 1986 (relating to treatment
5 of medical, dental, etc., expenses) is amended to read as
6 follows:

7 “(a) ALLOWANCE OF DEDUCTION.—There shall be
8 allowed as a deduction the expenses paid during the tax-
9 able year, not compensated for by insurance or otherwise,
10 for medical care of the taxpayer, his spouse, or a depend-
11 ent (as defined by section 152).”.

12 (b) DEDUCTION ALLOWED IN COMPUTING ADJUSTED GROSS INCOME.—Subsection (a) of section 62 of
13 such Code is amended by inserting after paragraph (18)
14 the following new paragraph:
15

16 “(19) MEDICAL CARE.—The deduction allowed
17 by section 213.”.

18 (c) CONFORMING AMENDMENTS.—

19 (1) Section 56(b)(1) of such Code is amended
20 by striking subparagraph (B).

21 (2) Section 67(b) is amended by striking para-
22 graph (5).

23 (3) Section 72(t)(B) of such Code is amended
24 by striking “to the extent such distributions do not
25 exceed the amount” and inserting “which are”.

1 (4) Sections 104(a) and 105(b) of such Code
 2 are both amended by striking “(and not in excess
 3 of)”.

4 (d) EFFECTIVE DATE.—The amendments made by
 5 this section shall apply to taxable years beginning after
 6 December 31, 2003.

7 **SEC. 103. MEDICAL CHECKING ACCOUNTS.**

8 (a) IN GENERAL.—Subchapter F of chapter 1 of the
 9 Internal Revenue Code of 1986 (relating to exempt organi-
 10 zations) is amended by adding at the end the following:

11 **“PART IX—MEDICAL CHECKING ACCOUNTS**

 “Sec. 530A. Medical checking accounts.

12 **“SEC. 530A. MEDICAL CHECKING ACCOUNTS.**

13 “(a) GENERAL RULE.—A medical checking account
 14 shall be exempt from taxation under this subtitle. Not-
 15 withstanding the preceding sentence, any medical checking
 16 account shall be subject to the taxes imposed by section
 17 511 (relating to imposition of tax on unrelated business
 18 income of charitable, etc., organizations). Rules similar to
 19 the rules of paragraphs (2) and (4) of section 408(e) shall
 20 apply to medical checking accounts, and any amount treat-
 21 ed as distributed under such rules shall be treated as not
 22 used to pay qualified medical expenses.

23 “(b) DEDUCTION FOR CONTRIBUTIONS.—

1 “(1) IN GENERAL.—In the case of an indi-
2 vidual, there shall be allowed as a deduction an
3 amount equal to the aggregate amount paid in cash
4 during the taxable year to a medical checking ac-
5 count of the taxpayer.

6 “(2) LIMITATIONS.—

7 “(A) MAXIMUM ANNUAL CONTRIBUTION.—
8 The deduction under paragraph (1) for a tax-
9 able year shall not exceed \$1,000 (\$2,000 in
10 the case of a joint return).

11 “(B) MAXIMUM ALLOWABLE DEDUCTION
12 BASED ON BALANCE IN ACCOUNT.—No deduc-
13 tion shall be allowed for a taxable year for any
14 amount contributed to a medical checking ac-
15 count if the sum of such amount plus the bal-
16 ance in the account determined as the end of
17 the taxable year would exceed \$2,000 (\$4,000
18 in the case of married individuals filing a joint
19 return, a surviving spouse, and a head of house-
20 hold).

21 “(c) CREDIT FOR CONTRIBUTIONS.—

22 “(1) IN GENERAL.—In the case of an indi-
23 vidual, there shall be allowed as a credit against the
24 tax imposed by this chapter for the taxable year an
25 amount equal to the credit amount with respect to

1 contributions made during the taxable year to the
 2 medical checking account of the taxpayer.

3 “(2) CREDIT AMOUNT.—For purposes of para-
 4 graph (1), the credit amount is the lesser of—

5 “(A) the total amount of contributions to
 6 the medical checking account for the taxable
 7 year reduced by the amount of contributions al-
 8 lowed as a deduction under subsection (b), and

9 “(B) \$1,000.

10 “(d) DEFINITIONS AND SPECIAL RULES.—For pur-
 11 poses of this section—

12 “(1) MEDICAL CHECKING ACCOUNT.—The term
 13 ‘medical checking account’ means a trust created or
 14 organized in the United States for the exclusive ben-
 15 efit of a qualified individual or his beneficiaries, but
 16 only if the written governing instrument creating the
 17 trust meets the following requirements:

18 “(A) Except in the case of a rollover con-
 19 tribution described in paragraph (4)(C), no con-
 20 tribution will be accepted unless it is in cash, or
 21 it exceeds \$1,000 (\$2,000 in the case of mar-
 22 ried individuals filing a joint return, a surviving
 23 spouse, and a head of household).

24 “(B) The trustee is a bank (as defined in
 25 section 408(n)), an insurance company (as de-

1 fined in section 816), or another person who
2 demonstrates to the satisfaction of the Sec-
3 retary that the manner in which such person
4 will administer the trust will be consistent with
5 the requirements of this section.

6 “(C) No part of the trust assets will be in-
7 vested in life insurance contracts.

8 “(D) The assets of the trust will not be
9 commingled with other property except in a
10 common trust fund or common investment
11 fund.

12 “(E) The interest of an individual in the
13 balance in his account is nonforfeitable.

14 “(2) QUALIFIED MEDICAL EXPENSES.—The
15 term ‘qualified medical expenses’ means, with re-
16 spect to an account holder, amounts paid by such
17 holder for medical care (as defined in section
18 213(d)) for such individual, the spouse of such indi-
19 vidual, and any dependent (as defined in section
20 152) of such individual, but only to the extent such
21 amounts are not compensated for by insurance or
22 otherwise (including distributions from an Archer
23 MSA which are not includible in gross income by
24 reason of section 220(f)(1)).

1 “(3) CHANGE IN FILING STATUS.—In the case
2 of a taxpayer whose filing status changes during the
3 taxable year, the limitation under subparagraph (B)
4 shall be apportioned among the filing statuses of the
5 taxpayer in accordance with regulations prescribed
6 by the Secretary.

7 “(4) CERTAIN RULES TO APPLY.—Rules similar
8 to the following rules shall apply for purposes of this
9 section:

10 “(A) Section 219(d)(2) (relating to no de-
11 duction for rollovers).

12 “(B) Section 219(f)(3) (relating to time
13 when contributions deemed made).

14 “(C) Section 219(f)(5) (relating to em-
15 ployer payments).

16 “(D) Section 220(f)(5) (relating to rollover
17 contributions).

18 “(E) Section 220(f)(7) (relating to trans-
19 fer of account incident to divorce).

20 “(F) Section 220(f)(8) (relating to treat-
21 ment after death of account holder).

22 “(G) Section 408(g) (relating to commu-
23 nity property laws).

24 “(H) Section 408(h) (relating to custodial
25 accounts).

1 “(e) TAX TREATMENT OF DISTRIBUTIONS.—

2 “(1) AMOUNTS USED FOR QUALIFIED MEDICAL
3 EXPENSES.—Any amount paid or distributed out of
4 a medical checking account which is used exclusively
5 to pay qualified medical expenses of any account
6 holder shall not be includible in gross income.

7 “(2) INCLUSION OF AMOUNTS NOT USED FOR
8 QUALIFIED MEDICAL EXPENSES.—Any amount paid
9 or distributed out of a medical checking account
10 which is not used exclusively to pay the qualified
11 medical expenses of the account holder shall be in-
12 cluded in the gross income of such holder.

13 “(3) ADDITIONAL TAX ON DISTRIBUTIONS NOT
14 USED FOR QUALIFIED MEDICAL EXPENSES.—For
15 purposes of this section, rules similar to the rules of
16 section 220(f)(4) shall apply.

17 “(4) COORDINATION WITH MEDICAL EXPENSE
18 DEDUCTION.—For purposes of determining the
19 amount of the deduction under section 213, any pay-
20 ment or distribution out of a medical checking ac-
21 count for qualified medical expenses shall not be
22 treated as an expense paid for medical care.

23 “(f) REPORTS.—The Secretary may require the
24 trustee of a medical checking account to make such re-
25 ports regarding such account to the Secretary and to the

1 account holder with respect to contributions, distributions,
 2 and such other matters as the Secretary determines appro-
 3 priate. The reports required by this subsection shall be
 4 filed at such time and in such manner and furnished to
 5 such individuals at such time and in such manner as may
 6 be required by the Secretary.”.

7 (b) TAX ON EXCESS CONTRIBUTIONS.—Section 4973
 8 of such Code (relating to tax on excess contributions to
 9 individual retirement accounts, certain section 403(b) con-
 10 tracts, and certain individual retirement annuities) is
 11 amended—

12 (1) in subsection (a) by striking “or” at the end
 13 of paragraph (3), by inserting “or” at the end of
 14 paragraph (4), and by inserting after paragraph (4)
 15 the following:

16 “(5) a medical checking account (within the
 17 meaning of section 530A(d)),”, and

18 (2) by adding at the end the following new sub-
 19 section:

20 “(g) EXCESS CONTRIBUTIONS TO MEDICAL CHECK-
 21 ING ACCOUNTS.—For purposes of this section, in the case
 22 of medical checking accounts (within the meaning of sec-
 23 tion 530A(d)), the term ‘excess contributions’ means the
 24 sum of—

1 “(1) the aggregate amount contributed for the
 2 taxable year to the accounts (other than rollover
 3 contributions referred to in section 530A(d)(4)(C))
 4 which is neither excludable from gross income under
 5 section 106(b) nor allowable as a deduction or credit
 6 under section 530A for such year, and

7 “(2) the amount determined under this sub-
 8 section for the preceding taxable year, reduced by
 9 the sum of—

10 “(A) the distributions out of the accounts
 11 which were included in gross income under sec-
 12 tion 530A(e)(2), and

13 “(B) the excess (if any) of—

14 “(i) the sum of the maximum amount
 15 allowable as a deduction or credit under
 16 section 530A (determined without regard
 17 to section 106(b)) for the taxable year,
 18 over

19 “(ii) the amount contributed to the
 20 accounts for the taxable year.

21 For purposes of this subsection, any contribution which
 22 is distributed out of the medical savings account in a dis-
 23 tribution to which section 530A(d)(4)(B) applies shall be
 24 treated as an amount not contributed.”.

25 (c) TAX ON PROHIBITED TRANSACTIONS.—

1 (1) Section 4975 of such Code (relating to tax
2 on prohibited transactions) is amended by adding at
3 the end of subsection (c) the following new para-
4 graph:

5 “(6) SPECIAL RULE FOR MEDICAL CHECKING
6 ACCOUNTS.—An individual for whose benefit a med-
7 ical checking account (within the meaning of section
8 530A(d)) is established shall be exempt from the tax
9 imposed by this section with respect to any trans-
10 action concerning such account (which would other-
11 wise be taxable under this section) if, with respect
12 to such transaction, the account ceases to be a med-
13 ical checking account by reason of the application of
14 section 530A(e)(2) to such account.”.

15 (2) Paragraph (1) of section 4975(e) of such
16 Code is amended by striking “or” at the end of sub-
17 paragraph (E), by redesignating subparagraph (F)
18 as subparagraph (G), and by inserting after sub-
19 paragraph (E) the following new subparagraph:

20 “(F) a medical checking account described
21 in section 530A(d), or”.

22 (d) FAILURE TO PROVIDE REPORTS ON MEDICAL
23 CHECKING ACCOUNTS.—Paragraph (2) of section 6693(a)
24 (relating to general rule on reports) is amended by strik-
25 ing “and” at the end of subparagraph (C), by striking the

1 period at the end of subparagraph (D) and inserting
 2 “, and”, and by inserting after subparagraph (D) the fol-
 3 lowing new subparagraph:

4 “(E) section 530A(g) (relating to medical
 5 savings accounts).”.

6 (e) CLERICAL AMENDMENT.—The table of parts for
 7 subchapter F of chapter 1 of such Code is amended by
 8 adding at the end the following new item:

“PART IX. MEDICAL CHECKING ACCOUNTS.”.

9 (f) EFFECTIVE DATE.—The amendments made by
 10 this section shall apply to taxable years beginning after
 11 December 31, 2003.

12 **SEC. 104. DECREASE IN MINIMUM ANNUAL DEDUCTIBLES**
 13 **UNDER A HIGH DEDUCTIBLE HEALTH PLAN**
 14 **FOR PURPOSES OF ARCHER MSAS.**

15 (a) IN GENERAL.—Subparagraph (A) of section
 16 220(c)(2) of the Internal Revenue Code of 1986 (defining
 17 high deductible health plan) is amended—

18 (1) in clause (i) by striking “\$1,500” and in-
 19 serting “\$1,000”, and

20 (2) in clause (ii) by striking “\$3,000” and in-
 21 serting “\$2,000”.

22 (b) MINIMUM NOT INCREASED BY INFLATION.—Sec-
 23 tion 220(g) of such Code is amended by inserting “(other
 24 than the \$1,000 amount in subparagraph (A)(i) and the

1 \$2,000 amount in subparagraph (A)(ii) thereof)” after
2 “subsection (c)(2)”.

3 (c) EFFECTIVE DATE.—The amendments made by
4 this section shall apply to taxable years beginning after
5 December 31, 2003.

6 **TITLE II—MEDICAL PRIVACY**

7 **SEC. 201. FINDINGS.**

8 The Congress finds the following:

9 (1) Medical privacy is an issue that concerns a
10 growing number of people in the United States. The
11 culture of the United States has always strongly fa-
12 vored a close physician-patient relationship. One of
13 the key elements of this relationship is the trust that
14 a patient has that their personal information will be
15 treated as confidential by medical personnel and will
16 not be made public or accessible to other persons
17 without their permission.

18 (2) In our increasingly complex times, two
19 trends are combining to exert pressure on maintain-
20 ing the confidentiality of health care information.
21 First, public policy favors an increased ability to
22 provide protection against harmful prescription
23 interactions and for the reporting of medications’ se-
24 rious side effects. Second, health care insurers desire
25 to take advantage of economies of scale in control-

1 ling health care costs. These trends have greatly re-
2 duced expectations for the privacy of health care in-
3 formation.

4 (3) For the first time in our Nation's history,
5 serious loopholes have been written into privacy pro-
6 tections that were created to protect the right of in-
7 dividuals. Positive changes in privacy law have been
8 made in recent years to guarantee that patients are
9 notified regarding the use of their health informa-
10 tion, have access to their own medical records, and
11 are able to request corrections of such records.
12 These protections must be maintained and strength-
13 ened.

14 (4) One of the greatest needs in the area of
15 health privacy is to protect individuals against the
16 use of their confidential health information for prof-
17 it-generating consumer marketing. Patients justifi-
18 ably have objections to this use of their information
19 without their consent.

20 (5) There recently have been implemented a se-
21 ries of alarming modifications to the standards pre-
22 viously finalized to protect the privacy of individually
23 identifiable health information. These include
24 changes in important definitions, additions to the
25 category of health care operations for which patient

1 consent for the use of their information is not re-
 2 quired, and changes in permitted use of patient in-
 3 formation without consent for public health pur-
 4 poses.

5 (6) Recent rollbacks in health privacy need to
 6 be reversed, and the individuals' confidence that
 7 their private conversations with medical personnel
 8 will remain private needs to be strengthened.

9 (7) There is also a need to protect the integrity
 10 and confidentiality of social security account num-
 11 bers and to prohibit Federal agencies from imposing
 12 national standards for identification of individuals.

13 **SEC. 202. MODIFICATION OF REGULATIONS ON PRIVACY OF**
 14 **INDIVIDUALLY IDENTIFIABLE HEALTH IN-**
 15 **FORMATION.**

16 (a) MARKETING.—

17 (1) IN GENERAL.—The modifications made by
 18 the August 2002 medical privacy rule to the defini-
 19 tion of the term “marketing” in section 164.501 of
 20 title 45, Code of Federal Regulations, shall have no
 21 force or effect.

22 (2) AUTHORIZATIONS FOR MARKETING.—Sec-
 23 tion 164.508 of title 45, Code of Federal Regula-
 24 tions, shall be construed and applied so as to require
 25 that, if an authorization is required for a use or dis-

1 closure of protected health information for mar-
2 keting, the authorization shall be considered invalid
3 unless it—

4 (A) uses the term “marketing”;

5 (B) states that the purpose of the use or
6 disclosure involved is marketing; and

7 (C) describes the specific marketing uses
8 and disclosures authorized.

9 (b) CONSENT FOR USES OR DISCLOSURES TO CARRY
10 OUT TREATMENT, PAYMENT, OR HEALTH CARE OPER-
11 ATIONS.—

12 (1) IN GENERAL.—The modifications made to
13 section 164.506 of title 45, Code of Federal Regula-
14 tions, by the August 2002 medical privacy rule shall
15 have no force or effect.

16 (2) USE OR DISCLOSURE WITHOUT CONSENT.—

17 (A) IN GENERAL.—Section 164.506 of title
18 45, Code of Federal Regulations, insofar as it
19 permits any use or disclosure of protected
20 health information without consent, shall have
21 no force or effect.

22 (B) CIRCUMSTANCES WHERE CONSENT
23 NOT REQUIRED.—A health care provider may
24 use or disclose an individual’s protected health
25 information without obtaining the prior consent

1 of the individual only in the following cir-
2 cumstances:

3 (i) To fill or dispense a prescription,
4 and to search for drug interactions related
5 to that prescription, if the health care pro-
6 vider obtains written consent from the in-
7 dividual as soon as practicable.

8 (ii) To carry out treatment of that in-
9 dividual if—

10 (I) the individual has not exe-
11 cuted a Universal Health Privacy
12 Declaration promulgated under sub-
13 paragraph (C);

14 (II) the individual and the health
15 care provider have not had in-person
16 communication regarding such treat-
17 ment; and

18 (III) obtaining consent would be
19 impracticable.

20 (C) UNIVERSAL HEALTH PRIVACY DEC-
21 LARATION.—

22 (i) IN GENERAL.—The Secretary of
23 Health and Human Services shall promul-
24 gate a document which shall be known as

1 the “Universal Health Privacy Declara-
2 tion”.

3 (ii) ELIGIBILITY.—A Universal
4 Health Privacy Declaration may be exe-
5 cuted by any individual who is a citizen of
6 the United States or an alien lawfully ad-
7 mitted to the United States for permanent
8 residence.

9 (iii) PURPOSE.—A Universal Health
10 Privacy Declaration, once executed by an
11 individual described in clause (ii) and not
12 revoked, shall be considered to prohibit, as
13 provided under subparagraph (B), a health
14 care provider from using or disclosing the
15 individual’s protected health information
16 for treatment without obtaining the prior
17 consent of the individual.

18 (iv) ENFORCEMENT.—There is estab-
19 lished in the Department of Health and
20 Human Services an Office of the Health
21 Privacy Ombudsman, which shall be head-
22 ed by an individual known as the “Health
23 Privacy Ombudsman”. The Health Privacy
24 Ombudsman shall be charged with inves-
25 tigating complaints submitted by individ-

1 uals described in clause (ii) regarding a
2 use or disclosure of protected health infor-
3 mation in violation of their Universal
4 Health Privacy Declaration.

5 (c) DISCLOSURES FOR LAW ENFORCEMENT PUR-
6 POSES.—Subparagraph (C) of section 164.506(f)(1)(ii) of
7 title 45, Code of Federal Regulations shall have no force
8 or effect.

9 (d) DEFINITIONS.—

10 (1) IN GENERAL.—For purposes of this section:

11 (A) DECEMBER 2000 MEDICAL PRIVACY
12 RULE.—The term “December 2000 medical pri-
13 vacy rule” means the final rule on standards
14 for privacy of individually identifiable health in-
15 formation published on December 28, 2000, in
16 the Federal Register (65 Fed. Reg. 82462), in-
17 cluding the provisions of title 45, Code of Fed-
18 eral Regulations, revised or added by such rule.

19 (B) AUGUST 2002 MEDICAL PRIVACY
20 RULE.—The term “August 2002 medical pri-
21 vacy rule” means the final rule, published on
22 August 14, 2002, in the Federal Register (67
23 Fed. Reg. 53182), that modified the December
24 2000 medical privacy rule.

1 (2) OTHER TERMS DEFINED.—For purposes of
2 this section:

3 (A) HEALTH CARE PROVIDER.—The term
4 “health care provider” shall have the meaning
5 given such term in section 160.103 of title 45,
6 Code of Federal Regulations, as contained in
7 the December 2000 medical privacy rule.

8 (B) DISCLOSURE; INDIVIDUAL; PROTECTED
9 HEALTH INFORMATION; TREATMENT; USE.—
10 The terms “disclosure”, “individual”, “pro-
11 tected health information”, “treatment”, and
12 “use” shall have the meaning given such terms
13 in section 164.501 of title 45, Code of Federal
14 Regulations, as contained in the December
15 2000 medical privacy rule.

16 **SEC. 203. RESTRICTIONS ON THE USE OF THE SOCIAL SE-**
17 **CURITY ACCOUNT NUMBER.**

18 (a) REPEAL OF PROVISIONS AUTHORIZING CERTAIN
19 USAGES OF THE SOCIAL SECURITY ACCOUNT NUMBER.—
20 Section 205(c)(2) of the Social Security Act (42 U.S.C.
21 405(c)(2)) is amended—

22 (1) in subparagraph (C), by striking “(C)(i) It
23 is the policy” and all that follows through clause
24 (vi);

1 (2) by striking clause (ix) of subparagraph (C)
 2 and redesignating clauses (vii) and (viii) of subpara-
 3 graph (C) as clauses (iv) and (v), respectively;

4 (3) by striking subparagraphs (E) and (H);

5 (4) by redesignating subparagraphs (F) and
 6 (G) as subparagraphs (E) and (F), respectively; and

7 (5) in subparagraph (E) (as redesignated by
 8 paragraph (4)), by inserting “(i)” after “(E)”, and
 9 by adding at the end the following new clause:

10 “(ii) No individual shall be treated under any provi-
 11 sion of law, rule, or regulation as required for any purpose
 12 to apply for assignment of a social security account num-
 13 ber for himself or herself or on behalf of any other indi-
 14 vidual, except as a condition for receipt of benefits under
 15 this title as provided in clause (i).”.

16 (b) NEW RULES APPLICABLE TO SOCIAL SECURITY
 17 ACCOUNT NUMBERS.—Section 205(c)(2) of such Act is
 18 amended further—

19 (1) by inserting after subparagraph (B) the fol-
 20 lowing:

21 “(C)(i) All social security account numbers
 22 issued under this subsection shall be randomly
 23 generated.

24 “(ii) Except as otherwise provided in this
 25 paragraph—

1 “(I) the social security account num-
2 ber issued under this subsection to any in-
3 dividual shall be the exclusive property of
4 such individual, and

5 “(II) the Social Security Administra-
6 tion shall not divulge the social security ac-
7 count number issued to any individual
8 under this subsection to any agency or in-
9 strumentality of the Federal Government,
10 to any State, political subdivision of a
11 State, or agency or instrumentality of a
12 State or political subdivision thereof, or to
13 any other individual.

14 “(iii) Clause (ii) shall not apply with re-
15 spect to the use of the social security account
16 number as an identifying number to the extent
17 provided in section 6109(d) of the Internal Rev-
18 enue Code of 1986 (relating to use of the social
19 security account number for social security and
20 related purposes).”.

21 (c) EFFECTIVE DATES AND RELATED RULES.—

22 (1) EFFECTIVE DATES.—Not later than 60
23 days after the date of the enactment of this Act, the
24 Commissioner of Social Security shall publish in the
25 Federal Register the date determined by the Com-

1 missioner, in consultation with the Secretary of the
2 Treasury, to be the earliest date thereafter by which
3 implementation of the amendments made by this
4 section is practicable. The amendments made by
5 subsection (a) shall take effect on the earlier of such
6 date or the date which occurs 5 years after the date
7 of the enactment of this Act. The amendments made
8 by subsection (b) shall apply with respect to social
9 security account numbers issued on or after such
10 earlier date. The amendments made by subsection
11 (c) shall apply with respect to calendar quarters and
12 taxable years beginning on or after such earlier date.

13 (2) REISSUANCE OF NUMBERS.—The Commis-
14 sioner of Social Security shall ensure that, not later
15 than 5 years after the date of the enactment of this
16 Act, all individuals who have been issued social secu-
17 rity account numbers under section 205(c) of the
18 Social Security Act as of the date prior to the earlier
19 date specified in paragraph (1) can request new so-
20 cial security account numbers in accordance with
21 such section as amended by this section. Upon
22 issuance of such new social security account num-
23 bers, any social security account numbers issued to
24 such individuals prior to such earlier date specified
25 in paragraph (1) shall be null and void and subject

1 to the requirements of section 205(c)(2)(C)(ii)(II) of
2 such Act, as amended by this section. Any individual
3 to whom, or on behalf of whom, such a new social
4 security account number has been issued pursuant
5 to a request made under this paragraph shall be ex-
6 empt from any requirement under the laws of the
7 United States or of any State or political subdivision
8 thereof, or under the rules and regulations of any
9 agency or instrumentality of the United States or
10 any State or political subdivision thereof, to divulge,
11 use, or acknowledge any social security account
12 number previously issued to such individual. All per-
13 sons who obtain new social security account numbers
14 under this Act are granted lawful immunity from
15 any Federal, State, or local government agency re-
16 quirement to divulge, use, or acknowledge previously
17 issued social security account numbers. Nothing in
18 this section or the amendments made thereby shall
19 be construed to preclude the Social Security Admin-
20 istration and the Secretary of the Treasury from
21 cross-referencing such social security account num-
22 bers newly issued to individuals pursuant to this
23 paragraph to the former social security account
24 numbers of such individuals for purposes of admin-
25 istering title II or title XVI of such Act or admin-

1 istering the Internal Revenue Code of 1986 in con-
2 nection with section 86, chapter 2, and subtitle C
3 thereof.

4 **SEC. 204. PROHIBITION OF GOVERNMENTWIDE UNIFORM**
5 **IDENTIFYING NUMBERS.**

6 (a) IN GENERAL.—Except as authorized under sec-
7 tion 205(c)(2) of the Social Security Act, any two agencies
8 or instrumentalities of the Federal Government may not
9 implement the same identifying number with respect to
10 any individual.

11 (b) IDENTIFYING NUMBERS.—For purposes of this
12 section—

13 (1) the term “identifying number”, with respect
14 to an individual means any combination of alpha-nu-
15 meric symbols which serves to identify such indi-
16 vidual; and

17 (2) any identifying number and any one or
18 more derivatives of such number shall be treated as
19 the same identifying number.

20 (c) EFFECTIVE DATE.—The provisions of this section
21 shall take effect January 1, 2005.

22 **SEC. 205. PROHIBITION OF GOVERNMENT-ESTABLISHED**
23 **IDENTIFIERS.**

24 (a) IN GENERAL.—Subject to subsection (b), a Fed-
25 eral agency may not—

1 (1) establish or mandate a uniform standard
2 for identification of an individual that is required to
3 be used by any other Federal agency, a State agen-
4 cy, or a private person for any purpose other than
5 the purpose of conducting the authorized activities
6 of the Federal agency establishing or mandating the
7 standard; or

8 (2) condition receipt of any Federal grant or
9 contract or other Federal funding on the adoption,
10 by a State, a State agency, or a political subdivision
11 of a State, of a uniform standard for identification
12 of an individual.

13 (b) TRANSACTIONS BETWEEN PRIVATE PERSONS.—
14 Notwithstanding subsection (a), a Federal agency may not
15 establish, mandate, or encourage the use of a uniform
16 standard for identification of an individual that is required
17 to be used within the agency, or by any other Federal
18 agency, a State agency, or a private person, for the pur-
19 pose of—

20 (1) investigating, monitoring, overseeing, or
21 otherwise regulating a transaction to which the Fed-
22 eral Government is not a party; or

23 (2) administrative simplification.

1 (c) AMENDMENT OF PRIVACY ACT OF 1974.—(1)
 2 Section 7 of the Privacy Act of 1974 (5 U.S.C. 552a note)
 3 is amended—

4 (A) in subsection (a)(2), by striking “respect
 5 to—” and all that follows through the end of sub-
 6 paragraph (B) and inserting “respect to any disclo-
 7 sure which is required by Federal statute.”; and

8 (B) in subsection (b), by inserting “Federal”
 9 before “statutory”.

10 (2) Section 205(c)(2)(C)(ii) of the Social Security Act
 11 (42 U.S.C. 405(c)(2)(C)(ii)) is amended by striking “, un-
 12 less section 7(a)” and all that follows through the end of
 13 the section and inserting a period.

14 (d) ENFORCEMENT.—

15 (1) AMENDMENTS RELATING TO PRIVACY ACT
 16 OF 1974.—Subsection (g) of section 552a of title 5,
 17 United States Code, is amended—

18 (A) in subparagraph (D), by inserting
 19 after “this section,” the following: “subsection
 20 (a) or (b) of section 207 of the Medical Inde-
 21 pendence, Privacy, and Innovation Act of 2003,
 22 or section 7 of the Privacy Act of 1974,”; and

23 (B) by adding at the end the following new
 24 paragraph:

1 “(6) For purposes of any suit brought under the pro-
 2 visions of subsection (g)(1)(D) for failure to comply with
 3 any provision of section 7 of the Privacy Act of 1974, the
 4 term ‘agency’ shall include an agency of a State or local
 5 government.”.

6 (2) CRIMINAL PENALTIES FOR MISUSE OF SO-
 7 CIAL SECURITY ACCOUNT NUMBERS.—Section
 8 208(a) of the Social Security Act (42 U.S.C. 408(a))
 9 is amended—

10 (A) by adding “or” at the end of para-
 11 graph (8); and

12 (B) by inserting after paragraph (8) the
 13 following new paragraph:

14 “(9) is a medical service provider or health in-
 15 surance issuer and—

16 “(A) uses a social security account number
 17 as a medical patient tracking number, patient
 18 record number, or prescription tracking num-
 19 ber; or

20 “(B) denies any person medical care or
 21 health insurance coverage based upon such per-
 22 son’s refusal to disclose his or her social secu-
 23 rity account number;”.

1 **TITLE III—MODIFICATIONS RE-**
2 **GARDING REGULATION OF**
3 **DRUGS UNDER FEDERAL**
4 **FOOD, DRUG, AND COSMETIC**
5 **ACT**

6 **SEC. 301. DEFINITION OF DRUG.**

7 Section 201(g)(1) of the Federal Food, Drug, and
8 Cosmetic Act (21 U.S.C. 321(g)(1)) is amended in the
9 first sentence by striking “and (B) articles intended” and
10 all that follows and inserting the following: “and (B) arti-
11 cles intended for use in the diagnosis, cure, or treatment
12 (but not mitigation or prevention) of disease in man or
13 other animals.”.

14 **SEC. 302. STRIKING OF EFFECTIVENESS REQUIREMENT;**
15 **MODIFICATIONS REGARDING PATENT LIST-**
16 **INGS, PATENT CERTIFICATIONS, AND THIRTY-**
17 **MONTH RULE.**

18 (a) STRIKING OF EFFECTIVENESS REQUIREMENT;
19 PROHIBITION AGAINST LISTING OF CERTAIN PATENTS.—

20 (1) IN GENERAL.—Section 505(b) of the Fed-
21 eral Food, Drug, and Cosmetic Act (21 U.S.C.
22 355(b)) is amended by striking “(b)(1)” and all that
23 follows through “clinical trials required by clause
24 (A).” and inserting the following:

25 “(b) APPLICATION.—

1 “(1) CONTENTS.—

2 “(A) IN GENERAL.—Any person may file
3 with the Secretary an application with respect
4 to any drug subject to the provisions of sub-
5 section (a). Such persons shall submit to the
6 Secretary as a part of the application—

7 “(i) full reports of investigations
8 which have been made to show whether or
9 not such drug is safe for use;

10 “(ii) a full list of the articles used as
11 components of such drug;

12 “(iii) a full statement of the composi-
13 tion of such drug;

14 “(iv) a full description of the methods
15 used in, and the facilities and controls
16 used for, the manufacture, processing, and
17 packing of such drug;

18 “(v) such samples of such drug and of
19 the articles used as components thereof as
20 the Secretary may require; and

21 “(vi) specimens of the labeling pro-
22 posed to be used for such drug.

23 “(B) PATENT INFORMATION.—

24 “(i) REQUIREMENT.—The applicant
25 shall file with the application the patent

1 number and the expiration date of any pat-
2 ent which claims the drug for which the
3 applicant submitted the application or
4 which claims a method of using such drug
5 and with respect to which a claim of patent
6 infringement could reasonably be asserted
7 if a person not licensed by the owner en-
8 gaged in the manufacture use, or sale of
9 the drug.

10 “(ii) TYPES OF PATENTS.—

11 “(I) PATENTS SUBJECT TO RE-
12 QUIREMENT.—The patents for which
13 information under clause (i) is re-
14 quired to be filed with the Secretary
15 are drug substance (ingredient) pat-
16 ents, drug product (formulation and
17 composition) patents, product by proc-
18 ess patents, and method of use pat-
19 ents.

20 “(II) PROHIBITION REGARDING
21 CERTAIN PATENTS.—Process patents,
22 patents claiming packaging, patents
23 claiming metabolites, and patents
24 claiming intermediates are not patents
25 described in subclause (I), and infor-

1 mation on such patents may not be
2 filed with the Secretary.

3 “(III) PATENT REGARDING DRUG
4 SUBSTANCE.—For patents that claim
5 the drug substance, the applicant
6 shall submit information only on pat-
7 ents that claim the drug substance
8 that is the subject of the pending or
9 approved application or that claim a
10 drug substance that is the same as
11 the active ingredient that is the sub-
12 ject of an approved or pending appli-
13 cation within the meaning of sub-
14 section (j)(2)(A)(ii).

15 “(IV) PATENT REGARDING DRUG
16 PRODUCT.—For patents that claim a
17 drug product, the applicant shall sub-
18 mit information only on those patents
19 that claim a drug product that is the
20 subject of a pending or approved ap-
21 plication.

22 “(V) PATENT REGARDING METH-
23 OD OF USE.—For patents that claim a
24 method of use, the applicant shall
25 submit information only on those pat-

1 ents that claim indications or other
2 conditions of use that are the subject
3 of a pending or approved application.
4 For approved applications, the appli-
5 cant shall identify the indication or
6 other condition of use in the approved
7 labeling that corresponds to the listed
8 patent and claim identified.

9 “(iii) FILING OF PATENT AFTER SUB-
10 MISSION OF APPLICATION.—If a applica-
11 tion is filed under this subsection for a
12 drug and a patent which claims such drug
13 or a method of using such drug is issued
14 after the filing date but before approval of
15 the application, the applicant shall amend
16 the application to include the information
17 required by clauses (i) and (ii).

18 “(iv) PUBLICATION OF PATENT IN-
19 FORMATION.—Upon approval of the appli-
20 cation, the Secretary shall publish informa-
21 tion submitted under clauses (i) through
22 (iii).

23 “(C) GUIDANCE REGARDING INCLUSION OF
24 WOMEN AND MINORITIES IN CLINICAL
25 TRIALS.—The Secretary shall, in consultation

1 with the Director of the National Institutes of
2 Health and with representatives of the drug
3 manufacturing industry, review and develop
4 guidance, as appropriate, on the inclusion of
5 women and minorities in clinical trials required
6 by subparagraph (A)(i).”.

7 (2) CONFORMING AMENDMENTS.—The Federal
8 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et
9 seq.) is amended—

10 (A) in section 201(p)—

11 (i) by striking “safety and effective-
12 ness of” and inserting “safety of”; and

13 (ii) by striking “safe and effective for
14 use” and inserting “safe for use”; and

15 (B) in section 505—

16 (i) by striking “safety and effective-
17 ness” each place such term appears and
18 inserting “safety”;

19 (ii) by striking “safety or effective-
20 ness” each place such term appears and
21 inserting “safety”; and

22 (iii) in subsection (i)(1)(D), by strik-
23 ing “pediatric safety and efficacy” and in-
24 serting “pediatric safety”.

1 (b) ABBREVIATED APPLICATIONS; SINGLE CERTIFI-
 2 CATION REGARDING PATENT INVALIDITY OR NON-
 3 INFRINGEMENT; SINGLE THIRTY-MONTH DELAY IN AP-
 4 PROVAL.—Section 505(j)(2)(A) of the Federal Food,
 5 Drug, and Cosmetic Act (21 U.S.C. 355(j)(2)(A)) is
 6 amended in the matter after and below clause (viii) by
 7 adding at the end the following sentence: “With respect
 8 to a certification under clause (vii)(IV), an abbreviated ap-
 9 plication (whether or not amended) may not contain more
 10 than one such certification, without regard to patents filed
 11 after the date of the certification.”.

12 **SEC. 303. IMPORTATION OF CERTAIN DRUGS.**

13 Chapter VIII of the Federal Food, Drug, and Cos-
 14 metic Act (21 U.S.C. 381 et seq.) is amended by striking
 15 section 804 and inserting the following:

16 “IMPORTATION OF CERTAIN DRUGS

17 “SEC. 804. (a) REGULATIONS.—The Secretary, after
 18 consultation with the United States Trade Representative
 19 and the Commissioner of Customs, shall promulgate regu-
 20 lations permitting pharmacists and wholesalers to import
 21 prescription drugs from foreign nations.

22 “(b) LIMITATION.—The regulations under subsection
 23 (a) shall require that safeguards be in place to ensure that
 24 each prescription drug imported under the regulations
 25 complies with section 505 (including being safe for the in-

1 tended use of the prescription drug) with sections 501 and
2 502 and with other applicable requirements of this Act.”.

○