

1 **TITLE V—PREVENTING FRAUD**
2 **AND ABUSE**
3 **Subtitle A—Establishment of New**
4 **Health and Human Services and**
5 **Department of Justice Health**
6 **Care Fraud Positions**

7 **SEC. 501. HEALTH AND HUMAN SERVICES SENIOR ADVISOR.**

8 Part C of title XXVII of the Public Health Service
9 Act (42 U.S.C. 300gg-91 et seq.) is amended—

10 (1) by redesignating section 2792 as section
11 2796; and

12 (2) by inserting after section 2791, the fol-
13 lowing:

14 **“SEC. 2792. SENIOR ADVISOR FOR HEALTH CARE FRAUD.**

15 “(a) ESTABLISHMENT.—The Secretary shall appoint
16 an individual to serve as the Senior Advisor for Health
17 Care Fraud (referred to in this section as the ‘Senior Ad-
18 visor’) within the Office of the Deputy Secretary. The Sen-
19 ior Advisory shall be the principal advisor on policy and
20 program development and oversight with respect to—

21 “(1) the detection and prevention of health care
22 fraud, waste, and abuse involving public and private
23 health insurance coverage; and

24 “(2) the coordination of anti-fraud efforts with-
25 in the Department of Health and Human Services

1 and with the Inspector General, the Department of
2 Justice, other Federal agencies as appropriate, State
3 and local law enforcement, State regulatory agen-
4 cies, and private health insurance coverage.

5 “(b) REQUIREMENTS.—The Senior Advisor shall—

6 “(1) not be subject to confirmation by the Sen-
7 ate or any committee or subcommittee of the Senate
8 or House of Representatives; and

9 “(2) be a Schedule C appointee and not be a
10 current career or career-conditional Federal execu-
11 tive branch employee, as defined in part 315 of
12 chapter I of title 5, Code of Federal Regulations.”.

13 **SEC. 502. DEPARTMENT OF JUSTICE POSITION.**

14 Chapter 41 of title 28, United States Code, is amend-
15 ed by adding at the end the following:

16 **“§ 614. Senior Counsel for Health Care Fraud En-
17 forcement**

18 “The Attorney General shall appoint an individual to
19 serve as the Senior Counsel for Health Care Fraud En-
20 forcement (referred to in this section as the ‘Senior Coun-
21 sel’) within the Office of the Deputy Attorney General to
22 serve as the principal advisor to the Attorney General on
23 policy and program development and oversight with re-
24 spect to—

1 “(1) the investigation and prosecution of health
2 care fraud and abuse involving public and private
3 health insurance coverage (as defined in section
4 2791 of the Public Health Service Act); and

5 “(2) the coordination of such efforts within the
6 Department of Justice and with the Inspector Gen-
7 eral, the Department of Health and Human Serv-
8 ices, other Federal agencies as appropriate, State
9 and local law enforcement, State regulatory agen-
10 cies, and private health insurance coverage.”.

11 **Subtitle B—Health Care Program**
12 **Integrity Coordinating Council**

13 **SEC. 511. ESTABLISHMENT.**

14 Part C of title XXVII of the Public Health Service
15 Act (42 U.S.C. 300gg-91 et seq.), as amended by section
16 501, is further amended by inserting after section 2793,
17 the following:

18 **“SEC. 2794. HEALTH CARE PROGRAM INTEGRITY COORDI-**
19 **NATING COUNCIL.**

20 “(a) ESTABLISHMENT.—There is established a coun-
21 cil to be known as the ‘Health Care Program Integrity
22 Coordinating Council’ (referred to in this section as the
23 ‘Council’).

24 “(b) MEMBERSHIP.—The Council shall be composed
25 of—

1 “(1) the Secretary of Health and Human Serv-
2 ices;

3 “(2) the Attorney General;

4 “(3) the Inspector General for the Department
5 of Health and Human Services;

6 “(4) the Secretary of Labor;

7 “(5) the Secretary of Defense;

8 “(6) the Director of the Office of Personnel
9 Management;

10 “(7) the Under Secretary for Health for the
11 Veterans Health Administration of the Department
12 of Veterans Affairs;

13 “(8) the Commissioner of the Social Security
14 Administration;

15 “(9) the President of the National Association
16 of Insurance Commissioners;

17 “(10) the President of the National Association
18 of Medicaid Fraud Control Units; and

19 “(11) any other member, the appointment of
20 whom a majority of the members of the Council de-
21 termines is necessary to carry out the **【Choices**
22 **Act?】**, except that an individual who is a representa-
23 tive of an entity subject to regulation under such
24 Act shall not be appointed under this subparagraph.

25 “(c) DUTIES.—The Council shall—

1 “(1) not later than 6 months after the date of
2 enactment of this section, develop a strategic plan
3 for improving the coordination and information shar-
4 ing among Federal agencies, State agencies, and pri-
5 vate health insurance coverage with respect to the
6 prevention, detection, and control of fraud, waste,
7 and abuse, including fraud and abuse of consumers
8 of the health care program or private health insur-
9 ance issuers;

10 “(2) annually submit to Congress a report on
11 actions taken to implement the strategic plan re-
12 quired under paragraph (1);

13 “(3) in carrying out the responsibilities identi-
14 fied under paragraph (1), evaluate ways to ensure
15 that private health insurance coverage is included in
16 investigative and data sharing programs, to the max-
17 imum extent feasible, with adequate protection pro-
18 vided for law enforcement-related data that is sen-
19 sitive because of concerns for the identities of crimi-
20 nal subjects or targets, and that recognizes that pri-
21 vate coverage may be responsible for fraud, waste,
22 and abuse of public and policyholder funds;

23 “(4) not later than 12 months after the date of
24 enactment of this section, develop and issue guide-
25 lines for purposes of carrying out the strategic plan

1 under paragraph (1), recognizing that fraudulent ac-
2 tivity in the health care system can affect both pub-
3 lic and private sector health insurance coverage, and
4 that the prevention, detection, investigation, and
5 prosecution of fraud against private health insurance
6 coverage is integral to the overall effort to combat
7 health care fraud;

8 “(5) at least once during every 5-year period,
9 update the strategic plan issued pursuant to para-
10 graph (1) and the guidelines issued pursuant to
11 paragraph (4);

12 “(6) develop recommendations, in consultation
13 with the Office of Management and Budget, for
14 measures to estimate the amount of fraud, waste,
15 and abuse in connection with public and private
16 health insurance coverage, and the annual savings
17 resulting from specific program integrity measures;

18 “(7) identify improvements needed for purposes
19 of information-sharing systems and activities used in
20 implementing the strategic plan under paragraph
21 (1); and

22 “(8) establish a consultative panel composed of
23 representatives of the private sector health insurance
24 industry and consult with this panel in the formula-
25 tion of Council recommendations.

1 “(d) EXEMPTIONS.—The Council shall be exempt
2 from—

3 “(1) sections 553, 556, and 557 of title 5,
4 United States Code, in the issuance of guidelines
5 pursuant to subsection (c)(4); and

6 “(2) the Federal Advisory Committee Act (5
7 U.S.C. app.) in order to protect against the release
8 of information which might undermine Federal,
9 State, or local health care fraud control efforts.

10 “(e) PUBLIC PARTICIPATION.—The Council shall
11 provide for reasonable public participation in matters be-
12 fore the Council to the extent that such participation
13 would not compromise the Council’s, or any other Federal,
14 State, or local government entity’s, efforts to control
15 health care fraud and abuse.”.

16 **Subtitle C—False Statements and**
17 **Representations**

18 **SEC. 521. PROHIBITION ON FALSE STATEMENTS AND REP-**
19 **RESENTATIONS.**

20 (a) PROHIBITION.—Part 5 of subtitle B of title I of
21 the Employee Retirement Income Security Act of 1974
22 (29 U.S.C. 1131 et seq.) is amended by adding at the end
23 the following:

1 **“SEC. 519. PROHIBITION ON FALSE STATEMENTS AND REP-**
2 **RESENTATIONS.**

3 “No person, in connection with a plan or other ar-
4 rangement that is multiple employer welfare arrangement
5 described in section 3(40), shall make a false statement
6 or false representation of fact, knowing it to be false, in
7 connection with the marketing or sale of such plan or ar-
8 rangement, to any employee, any member of an employee
9 organization, any beneficiary, any employer, any employee
10 organization, the Secretary, or any State, or the represent-
11 ative or agent of any such person, State, or the Secretary,
12 concerning—

13 “(1) the financial condition or solvency of such
14 plan or arrangement;

15 “(2) the benefits provided by such plan or ar-
16 rangement;

17 “(3) the regulatory status of such plan or other
18 arrangement under any Federal or State law gov-
19 erning collective bargaining, labor management rela-
20 tions, or intern union affairs; or

21 “(4) the regulatory status of such plan or other
22 arrangement regarding exemption from state regu-
23 latory authority under this Act.

24 This section shall not apply to any plan or arrangement
25 that does not fall within the meaning of the term ‘multiple
26 employer welfare arrangement’ under section 3(40(A)).”

1 (b) CRIMINAL PENALTIES.—Section 501 of the Em-
2 ployee Retirement Income Security Act of 1974 (29
3 U.S.C. 1131) is amended—

4 (1) by inserting “(a)” before “Any person”; and

5 (2) by adding at the end the following:

6 “(b) Any person that violates section 519 shall upon
7 conviction be imprisoned not more than 10 years or fined
8 under title 18, United States Code, or both.”.

9 (c) CONFORMING AMENDMENT.—The table of sec-
10 tions for part 5 of subtitle B of title I of the Employee
11 Retirement Income Security Act of 1974 is amended by
12 adding at the end the following:

“Sec. 519. Prohibition on false statement and representations.”.

13 **Subtitle D—Federal Health Care**
14 **Offense**

15 **SEC. 531. CLARIFYING DEFINITION.**

16 Section 24(a)(2) of title 18, United States Code, is
17 amended by inserting “or section 411, 518, or 511 of the
18 Employee Retirement Income Security Act of 1974,” after
19 “1954 of this title”.

20 **Subtitle E—Uniformity in Fraud**
21 **and Abuse Reporting**

22 **SEC. 541. DEVELOPMENT OF MODEL UNIFORM REPORT**
23 **FORM.**

24 Part C of title XXVII of the Public Health Service
25 Act (42 U.S.C. 300gg-91 et seq.), as amended by section

1 511, is further amended by inserting after section 2794,
2 the following:

3 **“SEC. 2795. UNIFORM FRAUD AND ABUSE REFERRAL FOR-**
4 **MAT.**

5 “The Secretary shall request the National Associa-
6 tion of Insurance Commissioners to develop a model uni-
7 form report form for private health insurance issuer seek-
8 ing to refer suspected fraud and abuse to State insurance
9 departments or other responsible State agencies for inves-
10 tigation. The Secretary shall request that the National As-
11 sociation of Insurance Commissioners develop rec-
12 ommendations for uniform reporting standards for such
13 referrals.”.

14 **Subtitle F—Applicability of State**
15 **Law to Combat Fraud and Abuse**

16 **SEC. 551. APPLICABILITY OF STATE LAW TO COMBAT**
17 **FRAUD AND ABUSE.**

18 (a) IN GENERAL.—Part 5 of subtitle B of title I of
19 the Employee Retirement Income Security Act of 1974
20 (29 U.S.C. 1131 et seq.), as amended by section 521, is
21 further amended by adding at the end the following:

22 **“SEC. 520. APPLICABILITY OF STATE LAW TO COMBAT**
23 **FRAUD AND ABUSE.**

24 “The Secretary may, for the purpose of identifying,
25 preventing, or prosecuting fraud and abuse, adopt regu-

1 latory standards establishing, or issue an order relating
2 to a specific person establishing, that a person engaged
3 in the business of providing insurance through a multiple
4 employer welfare arrangement described in section 3(40)
5 is subject to the laws of the States in which such person
6 operates which regulate insurance in such State, notwith-
7 standing section 514(b)(6) of this Act or the Liability Risk
8 Retention Act of 1986, and regardless of whether the law
9 of the State is otherwise preempted under any of such pro-
10 visions. This section shall not apply to any plan or ar-
11 rangement that does not fall within the meaning of the
12 term ‘multiple employer welfare arrangement’ under sec-
13 tion 3(40(A)).”.

14 (b) CONFORMING AMENDMENT.—The table of sec-
15 tions for part 5 of subtitle B of title I of the Employee
16 Retirement Income Security Act of 1974, as amended by
17 section 521, is further amended by adding at the end the
18 following:

“Sec. 520. Applicability of State law to combat fraud and abuse.”.

1 **Subtitle G—Enabling the Depart-**
2 **ment of Labor to Issue Adminis-**
3 **trative Summary Cease and De-**
4 **sist Orders and Summary Sei-**
5 **zures Orders Against Plans That**
6 **Are in Financially Hazardous**
7 **Condition**

8 **SEC. 561. ENABLING THE DEPARTMENT OF LABOR TO**
9 **ISSUE ADMINISTRATIVE SUMMARY CEASE**
10 **AND DESIST ORDERS AND SUMMARY SEI-**
11 **ZURES ORDERS AGAINST PLANS THAT ARE IN**
12 **FINANCIALLY HAZARDOUS CONDITION.**

13 (a) IN GENERAL.—Part 5 of subtitle B of title I of
14 the Employee Retirement Income Security Act of 1974
15 (29 U.S.C. 1131 et seq.), as amended by section 551, is
16 further amended by adding at the end the following:

17 **“SEC. 521. ADMINISTRATIVE SUMMARY CEASE AND DESIST**
18 **ORDERS AND SUMMARY SEIZURE ORDERS**
19 **AGAINST MULTIPLE EMPLOYER WELFARE**
20 **ARRANGEMENTS IN FINANCIALLY HAZ-**
21 **ARDOUS CONDITION.**

22 “(a) IN GENERAL.—The Secretary may issue a cease
23 and desist (ex parte) order under this title if it appears
24 to the Secretary that the alleged conduct of a multiple em-
25 ployer welfare arrangement described in section 3(40),

1 other than a plan or arrangement described in subsection
2 (g), is fraudulent, or creates an immediate danger to the
3 public safety or welfare, or is causing or can be reasonably
4 expected to cause significant, imminent, and irreparable
5 public injury.

6 “(b) HEARING.—A person that is adversely affected
7 by the issuance of a cease and desist order under sub-
8 section (a) may request a hearing by the Secretary regard-
9 ing such order. The Secretary may require that a pro-
10 ceeding under this section, including all related informa-
11 tion and evidence, be conducted in a confidential manner.

12 “(c) BURDEN OF PROOF.—The burden of proof in
13 any hearing conducted under subsection (b) shall be on
14 the party requesting the hearing to show cause why the
15 cease and desist order should be set aside.

16 “(d) DETERMINATION.—Based upon the evidence
17 presented at a hearing under subsection (b), the cease and
18 desist order involved may be affirmed, modified, or set
19 aside by the Secretary in whole or in part.

20 “(e) SEIZURE.—The Secretary may issue a summary
21 seizure order under this title if it appears that a multiple
22 employer welfare arrangement is in a financially haz-
23 ardous condition.

1 “(f) REGULATIONS.—The Secretary may promulgate
2 such regulations or other guidance as may be necessary
3 or appropriate to carry out this section.

4 “(g) EXCEPTION.—This section shall not apply to
5 any plan or arrangement that does not fall within the
6 meaning of the term ‘multiple employer welfare arrange-
7 ment’ under section 3(40(A)).”.

8 (b) CONFORMING AMENDMENT.—The table of sec-
9 tions for part 5 of subtitle B of title I of the Employee
10 Retirement Income Security Act of 1974, as amended by
11 section 551, is further amended by adding at the end the
12 following:

“Sec. 521. Administrative summary cease and desist orders and summary sei-
zure orders against health plans in financially hazardous condi-
tion.”.

13 **Subtitle H—Requiring Multiple**
14 **Employer Welfare Arrangement**
15 **(MEWA) Plans to File a Reg-**
16 **istration Form With the Depart-**
17 **ment of Labor Prior to Enroll-**
18 **ing Anyone in the Plan**

19 **SEC. 571. MEWA PLAN REGISTRATION WITH DEPARTMENT**
20 **OF LABOR.**

21 Section 101(g) of the Employee Retirement Income
22 Security Act of 1974 (29 U.S.C. 1021(g)) is amended—

23 (1) by striking “Secretary may” and inserting
24 “Secretary shall”; and

1 (2) by inserting “to register with the Secretary
2 prior to operating in a State and may, by regulation,
3 require such multiple employer welfare arrange-
4 ments” after “not group health plans”.

5 **Subtitle I—Permitting Evidentiary**
6 **Privilege and Confidential Com-**
7 **munications**

8 **SEC. 581. PERMITTING EVIDENTIARY PRIVILEGE AND CON-**
9 **FIDENTIAL COMMUNICATIONS.**

10 Section 504 of the Employee Retirement Income Se-
11 curity Act of 1974 (29 U.S.C. 1134) is amended by adding
12 at the end the following:

13 “(d) The Secretary may promulgate a regulation that
14 provides an evidentiary privilege for, and provides for the
15 confidentiality of communications between or among, any
16 of the following entities or their agents, consultants, or
17 employees:

18 “(1) A State insurance department.

19 “(2) A State attorney general.

20 “(3) The National Association of Insurance
21 Commissioners.

22 “(4) The Department of Labor.

23 “(5) The Department of the Treasury.

24 “(6) The Department of Justice.

1 “(7) The Department of Health and Human
2 Services.

3 “(8) Any other Federal or State authority that
4 the Secretary determines is appropriate for the pur-
5 poses of enforcing the provisions of this title.

6 “(e) The privilege established under subsection (d)
7 shall apply to communications related to any investigation,
8 audit, examination, or inquiry conducted or coordinated
9 by any of the agencies. A communication that is privileged
10 under subsection (d) shall not waive any privilege other-
11 wise available to the communicating agency or to any per-
12 son who provided the information that is communicated.”.

13 **TITLE VI—IMPROVING ACCESS**
14 **TO INNOVATIVE MEDICAL**
15 **THERAPIES**

16 **Subtitle A—Biologics Price**
17 **Competition and Innovation**

18

 【Policy under discussion】

19 **Subtitle B—More Affordable Medi-**
20 **cines for Children and Under-**
21 **served Communities**

22 **SEC. 611. EXPANDED PARTICIPATION IN 340B PROGRAM.**

23 (a) EXPANSION OF COVERED ENTITIES RECEIVING
24 DISCOUNTED PRICES.—Section 340B(a)(4) of the Public