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(Original Signature of Member)

113TH CONGRESS
2D SESSION

H. R.

To amend title XVIII of the Social Security Act to improve the integrity of the Medicare program, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. BRADY of Texas (for himself and Mr. McDERMOTT) introduced the following bill; which was referred to the Committee on

A BILL

To amend title XVIII of the Social Security Act to improve the integrity of the Medicare program, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Protecting the Integrity of Medicare Act of 2014”.

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

Sec. 1. Short title; table of contents.

- Sec. 2. Prohibition of inclusion of Social Security account numbers on Medicare cards.
- Sec. 3. Preventing wrongful Medicare payments for items and services furnished to incarcerated individuals, individuals not lawfully present, and deceased individuals.
- Sec. 4. Consideration of measures regarding Medicare beneficiary smart cards.
- Sec. 5. Modifying medicare durable medical equipment face-to-face encounter documentation requirement.
- Sec. 6. Reducing improper Medicare payments.
- Sec. 7. Improving senior Medicare patrol and fraud reporting rewards.
- Sec. 8. Requiring valid prescriber National Provider Identifiers on pharmacy claims.
- Sec. 9. Option to receive Medicare Summary Notice electronically.
- Sec. 10. Renewal of MAC contracts.
- Sec. 11. Study on pathway for incentives to States for State participation in medicaid data match program.
- Sec. 12. Programs to prevent prescription drug abuse under Medicare part D.
- Sec. 13. Guidance on application of Common Rule to clinical data registries.
- Sec. 14. Eliminating certain civil money penalties; gainsharing study and report.
- Sec. 15. Modification of Medicare home health surety bond condition of participation requirement.
- Sec. 16. Oversight of Medicare coverage of manual manipulation of the spine to correct subluxation.
- Sec. 17. Limiting payment amount under Medicare program for vacuum erection systems.
- Sec. 18. National expansion of prior authorization model for repetitive scheduled non-emergent ambulance transport.
- Sec. 19. Repealing duplicative Medicare secondary payor provision.
- Sec. 20. Plan for expanding data in annual CERT report.
- Sec. 21. Rule of construction.

1 **SEC. 2. PROHIBITION OF INCLUSION OF SOCIAL SECURITY**

2 **ACCOUNT NUMBERS ON MEDICARE CARDS.**

3 (a) IN GENERAL.—Section 205(c)(2)(C) of the Social
4 Security Act (42 U.S.C. 405(c)(2)(C)) is amended—

5 (1) by moving clause (x), as added by section
6 1414(a)(2) of the Patient Protection and Affordable
7 Care Act, 6 ems to the left;

8 (2) by redesignating clause (x), as added by
9 section 2(a)(1) of the Social Security Number Pro-
10 tection Act of 2010, and clause (xi) as clauses (xi)
11 and (xii), respectively; and

1 (3) by adding at the end the following new
2 clause:

3 “(xiii) The Secretary of Health and Human Services,
4 in consultation with the Commissioner of Social Security,
5 shall establish cost-effective procedures to ensure that a
6 Social Security account number (or derivative thereof) is
7 not displayed, coded, or embedded on the Medicare card
8 issued to an individual who is entitled to benefits under
9 part A of title XVIII or enrolled under part B of title
10 XVIII and that any other identifier displayed on such card
11 is not identifiable as a Social Security account number (or
12 derivative thereof).”.

13 (b) IMPLEMENTATION.—In implementing clause (xiii)
14 of section 205(c)(2)(C) of the Social Security Act (42
15 U.S.C. 405(c)(2)(C)), as added by subsection (a)(3), the
16 Secretary of Health and Human Services shall do the fol-
17 lowing:

18 (1) IN GENERAL.—Establish a cost-effective
19 process that involves the least amount of disruption
20 to, as well as necessary assistance for, Medicare
21 beneficiaries and health care providers, such as a
22 process that provides such beneficiaries with access
23 to assistance through a toll-free telephone number
24 and provides outreach to providers.

1 (2) CONSIDERATION OF MEDICARE BENE-
2 FICIARY IDENTIFIED.—Consider implementing a
3 process, similar to the process involving Railroad Re-
4 tirement Board beneficiaries, under which a Medi-
5 care beneficiary identifier which is not a Social Secu-
6 rity account number (or derivative thereof) is used
7 external to the Department of Health and Human
8 Services and is convertible over to a Social Security
9 account number (or derivative thereof) for use inter-
10 nal to such Department and the Social Security Ad-
11 ministration.

12 (c) FUNDING FOR IMPLEMENTATION.—For purposes
13 of implementing the provisions of and the amendments
14 made by this section, the Secretary of Health and Human
15 Services shall provide for the following transfers from the
16 Federal Hospital Insurance Trust Fund under section
17 1817 of the Social Security Act (42 U.S.C. 1395i) and
18 from the Federal Supplementary Medical Insurance Trust
19 Fund established under section 1841 of such Act (42
20 U.S.C. 1395t), in such proportions as the Secretary deter-
21 mines appropriate:

22 (1) To the Centers for Medicare & Medicaid
23 Program Management Account, transfers of the fol-
24 lowing amounts:

1 (A) For fiscal year 2015, \$65,000,000, to
2 be made available through fiscal year 2018.

3 (B) For each of fiscal years 2016 and
4 2017, \$53,000,000, to be made available
5 through fiscal year 2018.

6 (C) For fiscal year 2018, \$48,000,000, to
7 be made available until expended.

8 (2) To the Social Security Administration Limi-
9 tation on Administration Account, transfers of the
10 following amounts:

11 (A) For fiscal year 2015, \$27,000,000, to
12 be made available through fiscal year 2018.

13 (B) For each of fiscal years 2016 and
14 2017, \$22,000,000, to be made available
15 through fiscal year 2018.

16 (C) For fiscal year 2018, \$27,000,000, to
17 be made available until expended.

18 (3) To the Railroad Retirement Board Limita-
19 tion on Administration Account, the following
20 amount:

21 (A) For fiscal year 2015, \$3,000,000, to
22 be made available until expended.

23 (d) EFFECTIVE DATE.—

24 (1) IN GENERAL.—Clause (xiii) of section
25 205(c)(2)(C) of the Social Security Act (42 U.S.C.

1 405(c)(2)(C)), as added by subsection (a)(3), shall
2 apply with respect to Medicare cards issued on and
3 after an effective date specified by the Secretary of
4 Health and Human Services, but in no case shall
5 such effective date be later than the date that is four
6 years after the date of the enactment of this Act.

7 (2) REISSUANCE.—The Secretary shall provide
8 for the reissuance of Medicare cards that comply
9 with the requirements of such clause not later than
10 four years after the effective date specified by the
11 Secretary under paragraph (1).

12 **SEC. 3. PREVENTING WRONGFUL MEDICARE PAYMENTS**
13 **FOR ITEMS AND SERVICES FURNISHED TO IN-**
14 **CARCERATED INDIVIDUALS, INDIVIDUALS**
15 **NOT LAWFULLY PRESENT, AND DECEASED IN-**
16 **DIVIDUALS.**

17 (a) REQUIREMENT FOR THE SECRETARY TO ESTAB-
18 LISH POLICIES AND CLAIMS EDITS RELATING TO INCAR-
19 CERATED INDIVIDUALS, INDIVIDUALS NOT LAWFULLY
20 PRESENT, AND DECEASED INDIVIDUALS.—Section 1874
21 of the Social Security Act (42 U.S.C. 1395kk) is amended
22 by adding at the end the following new subsection:

23 “(f) REQUIREMENT FOR THE SECRETARY TO ESTAB-
24 LISH POLICIES AND CLAIMS EDITS RELATING TO INCAR-
25 CERATED INDIVIDUALS, INDIVIDUALS NOT LAWFULLY

1 PRESENT, AND DECEASED INDIVIDUALS.—The Secretary
2 shall establish and maintain procedures, including proce-
3 dures for using claims processing edits, updating eligibility
4 information to improve provider accessibility, and con-
5 ducting recoupment activities such as through recovery
6 audit contractors, in order to ensure that payment is not
7 made under this title for items and services furnished to
8 an individual who is one of the following:

9 “(1) An individual who is incarcerated.

10 “(2) An individual who is not lawfully present
11 in the United States and who is not eligible for cov-
12 erage under this title.

13 “(3) A deceased individual.”.

14 (b) REPORT.—Not later than 18 months after the
15 date of the enactment of this section, and periodically
16 thereafter as determined necessary by the Office of Inspec-
17 tor General of the Department of Health and Human
18 Services, such Office shall submit to Congress a report
19 on the activities described in subsection (f) of section 1874
20 of the Social Security Act (42 U.S.C. 1395kk), as added
21 by subparagraph (a), that have been conducted since such
22 date of enactment.

1 **SEC. 4. CONSIDERATION OF MEASURES REGARDING MEDI-**
2 **CARE BENEFICIARY SMART CARDS.**

3 To the extent the Secretary of Health and Human
4 Services determines that it is cost effective and techno-
5 logically viable to use electronic Medicare beneficiary and
6 provider cards (such as cards that use smart card tech-
7 nology, including an embedded and secure integrated cir-
8 cuit chip), as presented in the Government Accountability
9 Office report required by the conference report accom-
10 panying the Consolidated Appropriations Act, 2014 (Pub-
11 lic Law 113–76), the Secretary shall consider such meas-
12 ures as determined appropriate by the Secretary to imple-
13 ment such use of such cards for beneficiary and provider
14 use under title XVIII of the Social Security Act (42
15 U.S.C. 1395 et seq.). In the case that the Secretary con-
16 siders measures under the preceding sentence, the Sec-
17 retary shall submit to the Committees on Ways and Means
18 and on Energy and Commerce of the House of Represent-
19 atives, and to the Committee on Finance of the Senate,
20 a report outlining the considerations undertaken by the
21 Secretary under such sentence.

1 **SEC. 5. MODIFYING MEDICARE DURABLE MEDICAL EQUIP-**
2 **MENT FACE-TO-FACE ENCOUNTER DOCU-**
3 **MENTATION REQUIREMENT.**

4 (a) IN GENERAL.—Section 1834(a)(11)(B)(ii) of the
5 Social Security Act (42 U.S.C. 1395m(a)(11)(B)(ii)) is
6 amended—

7 (1) by striking “the physician documenting
8 that”; and

9 (2) by striking “has had a face-to-face encoun-
10 ter” and inserting “documenting such physician,
11 physician assistant, practitioner, or specialist has
12 had a face-to-face encounter”.

13 (b) IMPLEMENTATION.—Notwithstanding any other
14 provision of law, the Secretary of Health and Human
15 Services may implement the amendments made by sub-
16 section (a) by program instruction or otherwise.

17 **SEC. 6. REDUCING IMPROPER MEDICARE PAYMENTS.**

18 (a) MEDICARE ADMINISTRATIVE CONTRACTOR IM-
19 PROPER PAYMENT OUTREACH AND EDUCATION PRO-
20 GRAM.—

21 (1) IN GENERAL.—Section 1874A of the Social
22 Security Act (42 U.S.C. 1395kk-1) is amended—

23 (A) in subsection (a)(4)—

24 (i) by redesignating subparagraph (G)
25 as subparagraph (H); and

1 (ii) by inserting after subparagraph
2 (F) the following new subparagraph:

3 “(G) IMPROPER PAYMENT OUTREACH AND
4 EDUCATION PROGRAM.—Having in place an im-
5 proper payment outreach and education pro-
6 gram described in subsection (h).”; and

7 (B) by adding at the end the following new
8 subsection:

9 “(h) IMPROPER PAYMENT OUTREACH AND EDU-
10 CATION PROGRAM.—

11 “(1) IN GENERAL.—In order to reduce im-
12 proper payments under this title, each medicare ad-
13 ministrative contractor shall establish and have in
14 place an improper payment outreach and education
15 program under which the contractor, through out-
16 reach, education, training, and technical assistance
17 or other activities, shall provide providers of services
18 and suppliers located in the region covered by the
19 contract under this section with the information de-
20 scribed in paragraph (2). The activities described in
21 the preceding sentence shall be conducted on a reg-
22 ular basis.

23 “(2) INFORMATION TO BE PROVIDED THROUGH
24 ACTIVITIES.—The information to be provided under
25 such payment outreach and education program shall

1 include information the Secretary determines to be
2 appropriate which may include the following infor-
3 mation:

4 “(A) A list of the providers’ or suppliers’
5 most frequent and expensive payment errors
6 over the last quarter.

7 “(B) Specific instructions regarding how to
8 correct or avoid such errors in the future.

9 “(C) A notice of new topics that have been
10 approved by the Secretary for audits conducted
11 by recovery audit contractors under section
12 1893(h).

13 “(D) Specific instructions to prevent fu-
14 ture issues related to such new audits.

15 “(E) Other information determined appro-
16 priate by the Secretary.

17 “(3) PRIORITY.—A medicare administrative
18 contractor shall give priority to activities under such
19 program that will reduce improper payments that
20 are one or more of the following:

21 “(A) Are for items and services that have
22 the highest rate of improper payment.

23 “(B) Are for items and service that have
24 the greatest total dollar amount of improper
25 payments.

1 “(C) Are due to clear misapplication or
2 misinterpretation of Medicare policies.

3 “(D) Are clearly due to common and inad-
4 vertent clerical or administrative errors.

5 “(E) Are due to other types of errors that
6 the Secretary determines could be prevented
7 through activities under the program.

8 “(4) INFORMATION ON IMPROPER PAYMENTS
9 FROM RECOVERY AUDIT CONTRACTORS.—

10 “(A) IN GENERAL.—In order to assist
11 medicare administrative contractors in carrying
12 out improper payment outreach and education
13 programs, the Secretary shall provide each con-
14 tractor with a complete list of the types of im-
15 proper payments identified by recovery audit
16 contractors under section 1893(h) with respect
17 to providers of services and suppliers located in
18 the region covered by the contract under this
19 section. Such information shall be provided on
20 a time frame the Secretary determines appro-
21 priate which may be on a quarterly basis.

22 “(B) INFORMATION.—The information de-
23 scribed in subparagraph (A) shall include infor-
24 mation such as the following:

1 “(i) Providers of services and sup-
2 pliers that have the highest rate of im-
3 proper payments.

4 “(ii) Providers of services and sup-
5 pliers that have the greatest total dollar
6 amounts of improper payments.

7 “(iii) Items and services furnished in
8 the region that have the highest rates of
9 improper payments.

10 “(iv) Items and services furnished in
11 the region that are responsible for the
12 greatest total dollar amount of improper
13 payments.

14 “(v) Other information the Secretary
15 determines would assist the contractor in
16 carrying out the program.

17 “(5) COMMUNICATIONS.—Communications with
18 providers of services and suppliers under an im-
19 proper payment outreach and education program are
20 subject to the standards and requirements of sub-
21 section (g).”.

22 (b) USE OF CERTAIN FUNDS RECOVERED BY
23 RACs.—Section 1893(h) of the Social Security Act (42
24 U.S.C. 1395ddd(h)) is amended—

1 (1) in paragraph (2), by inserting “or section
2 1874(h)(6)” after “paragraph (1)(C)”; and

3 (2) by adding at the end the following new
4 paragraph:

5 “(10) USE OF CERTAIN RECOVERED FUNDS.—

6 “(A) IN GENERAL.—After application of
7 paragraph (1)(C), the Secretary shall retain a
8 portion of the amounts recovered by recovery
9 audit contractors for each year under this sec-
10 tion which shall be available to the program
11 management account of the Centers for Medi-
12 care & Medicaid Services for purposes of, sub-
13 ject to subparagraph (B), carrying out sections
14 1833(z), 1834(l)(16), and 1874A(a)(4)(G), car-
15 rying out section 16(b) of the Protecting the In-
16 tegrity of Medicare Act of 2014, and imple-
17 menting strategies (such as claims processing
18 edits) to help reduce the error rate of payments
19 under this title. The amounts retained under
20 the preceding sentence shall not exceed an
21 amount equal to 15 percent of the amounts re-
22 covered under this subsection, and shall remain
23 available until expended.

24 “(B) LIMITATION.—Except for uses that
25 support claims processing (including edits) or

1 system functionality for detecting fraud,
2 amounts retained under subparagraph (A) may
3 not be used for technological-related infrastruc-
4 ture, capital investments, or information sys-
5 tems.

6 “(C) NO REDUCTION IN PAYMENTS TO RE-
7 COVERY AUDIT CONTRACTORS.—Nothing in
8 subparagraph (A) shall reduce amounts avail-
9 able for payments to recovery audit contractors
10 under this subsection.”.

11 **SEC. 7. IMPROVING SENIOR MEDICARE PATROL AND**
12 **FRAUD REPORTING REWARDS.**

13 (a) IN GENERAL.—The Secretary of Health and
14 Human Services (in this section referred to as the “Sec-
15 retary”) shall develop a plan to revise the incentive pro-
16 gram under section 203(b) of the Health Insurance Port-
17 ability and Accountability Act of 1996 (42 U.S.C. 1395b-
18 5(b)) to encourage greater participation by individuals to
19 report fraud and abuse in the Medicare program. Such
20 plan shall include recommendations for—

21 (1) ways to enhance rewards for individuals re-
22 porting under the incentive program, including re-
23 wards based on information that leads to an admin-
24 istrative action; and

1 (2) extending the incentive program to the
2 Medicaid program.

3 (b) PUBLIC AWARENESS AND EDUCATION CAM-
4 PAIGN.—The plan developed under subsection (a) shall
5 also include recommendations for the use of the Senior
6 Medicare Patrols authorized under section 411 of the
7 Older Americans Act of 1965 (42 U.S.C. 3032) to conduct
8 a public awareness and education campaign to encourage
9 participation in the revised incentive program under sub-
10 section (a).

11 (c) SUBMISSION OF PLAN.—Not later than 180 days
12 after the date of enactment of this Act, the Secretary shall
13 submit to Congress the plan developed under subsection
14 (a).

15 **SEC. 8. REQUIRING VALID PRESCRIBER NATIONAL PRO-**
16 **VIDER IDENTIFIERS ON PHARMACY CLAIMS.**

17 Section 1860D–4(c) of the Social Security Act (42
18 U.S.C. 1395w–104(c)) is amended by adding at the end
19 the following new paragraph:

20 “(4) REQUIRING VALID PRESCRIBER NATIONAL
21 PROVIDER IDENTIFIERS ON PHARMACY CLAIMS.—

22 “(A) IN GENERAL.—For plan year 2016
23 and subsequent plan years, the Secretary shall
24 require a claim for a covered part D drug for
25 a part D eligible individual enrolled in a pre-

1 description drug plan under this part or an MA-
2 PD plan under part C to include a prescriber
3 National Provider Identifier that is determined
4 to be valid under the procedures established
5 under subparagraph (B)(i).

6 “(B) PROCEDURES.—

7 “(i) VALIDITY OF PRESCRIBER NA-
8 TIONAL PROVIDER IDENTIFIERS.—The
9 Secretary, in consultation with appropriate
10 stakeholders, shall establish procedures for
11 determining the validity of prescriber Na-
12 tional Provider Identifiers under subpara-
13 graph (A).

14 “(ii) INFORMING BENEFICIARIES OF
15 REASON FOR DENIAL.—The Secretary shall
16 establish procedures to ensure that, in the
17 case that a claim for a covered part D
18 drug of an individual described in
19 subparagraph (A) is denied because the
20 claim does not meet the requirements of
21 this paragraph, the individual is properly
22 informed at the point of service of the rea-
23 son for the denial.

24 “(C) REPORT.—Not later than January 1,
25 2018, the Inspector General of the Department

1 of Health and Human Services shall submit to
2 Congress a report on the effectiveness of the
3 procedures established under subparagraph
4 (B)(i).”.

5 **SEC. 9. OPTION TO RECEIVE MEDICARE SUMMARY NOTICE**
6 **ELECTRONICALLY.**

7 (a) IN GENERAL.—Section 1806 of the Social Secu-
8 rity Act (42 U.S.C. 1395b–7) is amended by adding at
9 the end the following new subsection:

10 “(c) FORMAT OF STATEMENTS FROM SECRETARY.—

11 “(1) ELECTRONIC OPTION BEGINNING IN
12 2016.—Subject to paragraph (2), for statements de-
13 scribed in subsection (a) that are furnished for a pe-
14 riod in 2016 or a subsequent year, in the case that
15 an individual described in subsection (a) elects, in
16 accordance with such form, manner, and time speci-
17 fied by the Secretary, to receive such statement in
18 an electronic format, such statement shall be fur-
19 nished to such individual for each period subsequent
20 to such election in such a format and shall not be
21 mailed to the individual.

22 “(2) LIMITATION ON REVOCATION OPTION.—

23 “(A) IN GENERAL.—Subject to subpara-
24 graph (B), the Secretary may determine a max-
25 imum number of elections described in para-

1 graph (1) by an individual that may be revoked
2 by the individual.

3 “(B) MINIMUM OF ONE REVOCATION OP-
4 TION.—In no case may the Secretary determine
5 a maximum number under subparagraph (A)
6 that is less than one.

7 “(3) NOTIFICATION.—The Secretary shall en-
8 sure that, in the most cost effective manner and be-
9 ginning January 1, 2017, a clear notification of the
10 option to elect to receive statements described in
11 subsection (a) in an electronic format is made avail-
12 able, such as through the notices distributed under
13 section 1804, to individuals described in subsection
14 (a).”.

15 (b) ENCOURAGED EXPANSION OF ELECTRONIC
16 STATEMENTS.—To the extent to which the Secretary of
17 Health and Human Services determines appropriate, the
18 Secretary shall—

19 (1) apply an option similar to the option de-
20 scribed in subsection (c)(1) of section 1806 of the
21 Social Security Act (42 U.S.C. 1395b–7) (relating to
22 the provision of the Medicare Summary Notice in an
23 electronic format), as added by subsection (a), to
24 other statements and notifications under title XVIII
25 of such Act (42 U.S.C. 1395 et seq.); and

1 (2) provide such Medicare Summary Notice and
2 any such other statements and notifications on a
3 more frequent basis than is otherwise required under
4 such title.

5 **SEC. 10. RENEWAL OF MAC CONTRACTS.**

6 (a) IN GENERAL.—Section 1874A(b)(1)(B) of the
7 Social Security Act (42 U.S.C. 1395kk–1(b)(1)(B)) is
8 amended by striking “5 years” and inserting “10 years”.

9 (b) APPLICATION.—The amendments made by sub-
10 section (a) shall apply to contracts entered into on or
11 after, and to contracts in effect as of, the date of the en-
12 actment of this Act.

13 (c) CONTRACTOR PERFORMANCE TRANSPARENCY.—
14 Section 1874A(b)(3)(A) of the Social Security Act (42
15 U.S.C. 1395kk–1(b)(3)(A)) is amended by adding at the
16 end the following new clause:

17 “(iv) CONTRACTOR PERFORMANCE
18 TRANSPARENCY.—To the extent possible
19 without compromising the process for en-
20 tering into and renewing contracts with
21 medicare administrative contractors under
22 this section, the Secretary shall make
23 available to the public the performance of
24 each medicare administrative contractor

1 with respect to such performance require-
2 ments and measurement standards.”.

3 **SEC. 11. STUDY ON PATHWAY FOR INCENTIVES TO STATES**
4 **FOR STATE PARTICIPATION IN MEDICAID**
5 **DATA MATCH PROGRAM.**

6 Section 1893(g) of the Social Security Act (42 U.S.C.
7 1395ddd(g)) is amended by adding at the end the fol-
8 lowing new paragraph:

9 “(3) INCENTIVES FOR STATES.—The Secretary
10 shall study and, as appropriate, may specify incen-
11 tives for States to work with the Secretary for the
12 purposes described in paragraph (1)(A)(ii). The ap-
13 plication of the previous sentence may include use of
14 the waiver authority described in paragraph (2).”.

15 **SEC. 12. PROGRAMS TO PREVENT PRESCRIPTION DRUG**
16 **ABUSE UNDER MEDICARE PART D.**

17 (a) DRUG MANAGEMENT PROGRAM FOR AT-RISK
18 BENEFICIARIES.—

19 (1) IN GENERAL.—Section 1860D–4(c) of the
20 Social Security Act (42 U.S.C. 1395w–10(c)), as
21 amended by section 8, is further amended by adding
22 at the end the following:

23 “(5) DRUG MANAGEMENT PROGRAM FOR AT-
24 RISK BENEFICIARIES.—

1 “(A) AUTHORITY TO ESTABLISH.—A PDP
2 sponsor may establish a drug management pro-
3 gram for at-risk beneficiaries under which, sub-
4 ject to subparagraph (B), the PDP sponsor
5 may, in the case of an at-risk beneficiary for
6 prescription drug abuse who is an enrollee in a
7 prescription drug plan of such PDP sponsor,
8 limit such beneficiary’s access to coverage for
9 frequently abused drugs under such plan to fre-
10 quently abused drugs that are prescribed for
11 such beneficiary by a prescriber selected under
12 subparagraph (D), and dispensed for such bene-
13 ficiary by a pharmacy selected under such sub-
14 paragraph.

15 “(B) REQUIREMENT FOR NOTICES.—

16 “(i) IN GENERAL.—A PDP sponsor
17 may not limit the access of an at-risk ben-
18 eficiary for prescription drug abuse to cov-
19 erage for frequently abused drugs under a
20 prescription drug plan until such spon-
21 sor—

22 “(I) provides to the beneficiary
23 an initial notice described in clause
24 (ii) and a second notice described in
25 clause (iii); and

1 “(II) verifies with the providers
2 of the beneficiary that the beneficiary
3 is an at-risk beneficiary for prescrip-
4 tion drug abuse.

5 “(ii) INITIAL NOTICE.—An initial no-
6 tice described in this clause is a notice that
7 provides to the beneficiary—

8 “(I) notice that the PDP sponsor
9 has identified the beneficiary as po-
10 tentially being an at-risk beneficiary
11 for prescription drug abuse;

12 “(II) information describing all
13 State and Federal public health re-
14 sources that are designed to address
15 prescription drug abuse to which the
16 beneficiary has access, including men-
17 tal health services and other coun-
18 seling services;

19 “(III) notice of, and information
20 about, the right of the beneficiary to
21 appeal such identification under sub-
22 section (h) and the option of an auto-
23 matic escalation to external review;

24 “(IV) a request for the bene-
25 ficiary to submit to the PDP sponsor

1 preferences for which prescribers and
2 pharmacies the beneficiary would pre-
3 fer the PDP sponsor to select under
4 subparagraph (D) in the case that the
5 beneficiary is identified as an at-risk
6 beneficiary for prescription drug
7 abuse as described in clause (iii)(I);

8 “(V) an explanation of the mean-
9 ing and consequences of the identi-
10 fication of the beneficiary as poten-
11 tially being an at-risk beneficiary for
12 prescription drug abuse, including an
13 explanation of the drug management
14 program established by the PDP
15 sponsor pursuant to subparagraph
16 (A);

17 “(VI) clear instructions that ex-
18 plain how the beneficiary can contact
19 the PDP sponsor in order to submit
20 to the PDP sponsor the preferences
21 described in subclause (IV) and any
22 other communications relating to the
23 drug management program for at-risk
24 beneficiaries established by the PDP
25 sponsor; and

1 “(VII) contact information for
2 other organizations that can provide
3 the beneficiary with assistance regard-
4 ing such drug management program
5 (similar to the information provided
6 by the Secretary in other standardized
7 notices provided to part D eligible in-
8 dividuals enrolled in prescription drug
9 plans under this part).

10 “(iii) SECOND NOTICE.—A second no-
11 tice described in this clause is a notice that
12 provides to the beneficiary notice—

13 “(I) that the PDP sponsor has
14 identified the beneficiary as an at-risk
15 beneficiary for prescription drug
16 abuse;

17 “(II) that such beneficiary is
18 subject to the requirements of the
19 drug management program for at-risk
20 beneficiaries established by such PDP
21 sponsor for such plan;

22 “(III) of the prescriber and phar-
23 macy selected for such individual
24 under subparagraph (D);

1 “(IV) of, and information about,
2 the beneficiary’s right to appeal such
3 identification under subsection (h)
4 and the option of an automatic esca-
5 lation to external review;

6 “(V) that the beneficiary can, in
7 the case that the beneficiary has not
8 previously submitted to the PDP
9 sponsor preferences for which pre-
10 scribers and pharmacies the bene-
11 ficiary would prefer the PDP sponsor
12 select under subparagraph (D), sub-
13 mit such preferences to the PDP
14 sponsor; and

15 “(VI) that includes clear instruc-
16 tions that explain how the beneficiary
17 can contact the PDP sponsor.

18 “(iv) TIMING OF NOTICES.—

19 “(I) IN GENERAL.—Subject to
20 subclause (II), a second notice de-
21 scribed in clause (iii) shall be provided
22 to the beneficiary on a date that is
23 not less than 60 days after an initial
24 notice described in clause (ii) is pro-
25 vided to the beneficiary.

1 “(II) EXCEPTION.—In the case
2 that the PDP sponsor, in conjunction
3 with the Secretary, determines that
4 concerns identified through rule-
5 making by the Secretary regarding
6 the health or safety of the beneficiary
7 or regarding significant drug diversion
8 activities require the PDP sponsor to
9 provide a second notice described in
10 clause (iii) to the beneficiary on a
11 date that is earlier than the date de-
12 scribed in subclause (II), the PDP
13 sponsor may provide such second no-
14 tice on such earlier date.

15 “(C) AT-RISK BENEFICIARY FOR PRE-
16 SCRIPTION DRUG ABUSE.—

17 “(i) IN GENERAL.—For purposes of
18 this paragraph, the term ‘at-risk bene-
19 ficiary for prescription drug abuse’ means
20 a part D eligible individual who is not an
21 exempted individual described in clause (ii)
22 and—

23 “(I) who is identified through the
24 use of guidelines developed by the
25 Secretary in consultation with PDP

1 sponsors and other stakeholders de-
2 scribed in section 12(f)(2)(A) of the
3 Protecting the Integrity of Medicare
4 Act of 2014; or

5 “(II) with respect to whom the
6 PDP sponsor of a prescription drug
7 plan, upon enrolling such individual in
8 such plan, received notice from the
9 Secretary that such individual was
10 identified under this paragraph to be
11 an at-risk beneficiary for prescription
12 drug abuse under the prescription
13 drug plan in which such individual
14 was most recently previously enrolled
15 and such identification has not been
16 terminated under subparagraph (F).

17 “(ii) EXEMPTED INDIVIDUAL DE-
18 SCRIBED.—An exempted individual de-
19 scribed in this clause is an individual
20 who—

21 “(I) receives hospice care under
22 this title; or

23 “(II) the Secretary elects to treat
24 as an exempted individual for pur-
25 poses of clause (i).

1 “(D) SELECTION OF PRESCRIBERS.—

2 “(i) IN GENERAL.—With respect to
3 each at-risk beneficiary for prescription
4 drug abuse enrolled in a prescription drug
5 plan offered by such sponsor, a PDP spon-
6 sor shall, based on the preferences sub-
7 mitted to the PDP sponsor by the bene-
8 ficiary pursuant to clauses (ii)(IV) and
9 (iii)(V) of subparagraph (B), select—

10 “(I) one or more individuals who
11 are authorized to prescribe frequently
12 abused drugs (referred to in this
13 paragraph as ‘prescribers’) who may
14 write prescriptions for such drugs for
15 such beneficiary; and

16 “(II) one or more pharmacies
17 that may dispense such drugs to such
18 beneficiary.

19 “(ii) REASONABLE ACCESS.—In mak-
20 ing the selection under this subparagraph,
21 a PDP sponsor shall ensure that the bene-
22 ficiary continues to have reasonable access
23 to drugs described in subparagraph (G),
24 taking into account geographic location,

1 beneficiary preference, affordability, and
2 reasonable travel time.

3 “(iii) BENEFICIARY PREFERENCES.—

4 “(I) IN GENERAL.—If an at-risk
5 beneficiary for prescription drug
6 abuse submits preferences for which
7 in-network prescribers and pharmacies
8 the beneficiary would prefer the PDP
9 sponsor select in response to a notice
10 under subparagraph (B), the PDP
11 sponsor shall—

12 “(aa) review such pref-
13 erences;

14 “(bb) select or change the
15 selection of a prescriber or phar-
16 macy for the beneficiary based on
17 such preferences; and

18 “(cc) inform the beneficiary
19 of such selection or change of se-
20 lection.

21 “(II) EXCEPTION.—In the case
22 that the PDP sponsor determines that
23 a change to the selection of a pre-
24 scriber or pharmacy under item (bb)
25 by the PDP sponsor is contributing or

1 would contribute to prescription drug
2 abuse or drug diversion by the bene-
3 ficiary, the PDP sponsor may change
4 the selection of a prescriber or phar-
5 macy for the beneficiary without re-
6 gard to the preferences of the bene-
7 ficiary described in subclause (I).

8 “(iv) CONFIRMATION.—Before select-
9 ing a prescriber or pharmacy under this
10 subparagraph, a PDP sponsor must re-
11 quest and receive confirmation from the
12 prescriber or pharmacy acknowledging and
13 accepting that the beneficiary involved is in
14 the drug management program for at-risk
15 beneficiaries.

16 “(E) TERMINATIONS AND APPEALS.—The
17 identification of an individual as an at-risk ben-
18 eficiary for prescription drug abuse under this
19 paragraph, a coverage determination made
20 under a drug management program for at-risk
21 beneficiaries, and the selection of a prescriber
22 or pharmacy under subparagraph (D) with re-
23 spect to such individual shall be subject to re-
24 consideration and appeal under subsection (h)
25 and the option of an automatic escalation to ex-

1 ternal review to the extent provided by the Sec-
2 retary.

3 “(F) TERMINATION OF IDENTIFICATION.—

4 “(i) IN GENERAL.—The Secretary
5 shall develop standards for the termination
6 of identification of an individual as an at-
7 risk beneficiary for prescription drug abuse
8 under this paragraph. Under such stand-
9 ards such identification shall terminate as
10 of the earlier of—

11 “(I) the date the individual dem-
12 onstrates that the individual is no
13 longer likely, in the absence of the re-
14 strictions under this paragraph, to be
15 an at-risk beneficiary for prescription
16 drug abuse described in subparagraph
17 (C)(i); or

18 “(II) the end of such maximum
19 period of identification as the Sec-
20 retary may specify.

21 “(ii) RULE OF CONSTRUCTION.—

22 Nothing in clause (i) shall be construed as
23 preventing a plan from identifying an indi-
24 vidual as an at-risk beneficiary for pre-
25 scription drug abuse under subparagraph

1 (C)(i) after such termination on the basis
2 of additional information on drug use oc-
3 ccurring after the date of notice of such ter-
4 mination.

5 “(G) FREQUENTLY ABUSED DRUG.—For
6 purposes of this subsection, the term ‘frequently
7 abused drug’ means a drug that is determined
8 by the Secretary to be frequently abused or di-
9 verted and that is—

10 “(i) a Controlled Drug Substance in
11 Schedule CII-CIV;

12 “(ii) within the same class or category
13 of drugs as a Controlled Drug Substance
14 in Schedule CII-CIV; or

15 “(iii) within another class or category
16 of drugs that the Secretary determines, in
17 consultation with the Inspector General of
18 the Department of Health and Human
19 Services, is at high risk for diversion or
20 abuse.

21 “(H) DATA DISCLOSURE.—In the case of
22 an at-risk beneficiary for prescription drug
23 abuse whose access to coverage for frequently
24 abused drugs under a prescription drug plan
25 has been limited by a PDP sponsor under this

1 paragraph, such PDP sponsor shall disclose
2 data, including any necessary individually iden-
3 tifiable health information, in a form and man-
4 ner specified by the Secretary, about the deci-
5 sion to impose such limitations and the limita-
6 tions imposed by the sponsor under this part.

7 “(I) EDUCATION.—The Secretary shall
8 provide education to enrollees in prescription
9 drug plans of PDP sponsors and providers re-
10 garding the drug management program for at-
11 risk beneficiaries described in this paragraph,
12 including education—

13 “(i) provided by medicare administra-
14 tive contractors through the improper pay-
15 ment outreach and education program de-
16 scribed in section 1874A(h); and

17 “(ii) through current education efforts
18 (such as State health insurance assistance
19 programs described in subsection (a)(1)(A)
20 of section 119 of the Medicare Improve-
21 ments for Patients and Providers Act of
22 2008 (42 U.S.C. 1395b–3 note)) and ma-
23 terials directed toward such enrollees.”.

24 (2) INFORMATION FOR CONSUMERS.—Section
25 1860D–4(a)(1)(B) of the Social Security Act (42

1 U.S.C. 1395w-104(a)(1)(B)) is amended by adding
2 at the end the following:

3 “(v) The drug management program
4 for at-risk beneficiaries under subsection
5 (c)(5).”.

6 (b) UTILIZATION MANAGEMENT PROGRAMS.—Sec-
7 tion 1860D-4(c) of the Social Security Act (42 U.S.C.
8 1395w-104(c)), as amended by subsection (a) and section
9 8, is further amended—

10 (1) in paragraph (1), by inserting after sub-
11 paragraph (D) the following new subparagraph:

12 “(E) A utilization management tool to pre-
13 vent drug abuse (as described in paragraph
14 (6)(A)).”; and

15 (2) by adding at the end the following new
16 paragraph:

17 “(6) UTILIZATION MANAGEMENT TOOL TO PRE-
18 VENT DRUG ABUSE.—

19 “(A) IN GENERAL.—A tool described in
20 this paragraph is any of the following:

21 “(i) A utilization tool designed to pre-
22 vent the abuse of frequently abused drugs
23 by individuals and to prevent the diversion
24 of such drugs at pharmacies.

1 “(ii) Retrospective utilization review
2 to identify—

3 “(I) individuals that receive fre-
4 quently abused drugs at a frequency
5 or in amounts that are not clinically
6 appropriate; and

7 “(II) providers of services or sup-
8 pliers that may facilitate the abuse or
9 diversion of frequently abused drugs
10 by beneficiaries.

11 “(iii) Consultation with the Con-
12 tractor described in subparagraph (B) to
13 verify if an individual enrolling in a pre-
14 scription drug plan offered by a PDP
15 sponsor has been previously identified by
16 another PDP sponsor as an individual de-
17 scribed in clause (ii)(I).

18 “(B) REPORTING.—A PDP sponsor offer-
19 ing a prescription drug plan in a State shall
20 submit to the Secretary and the Medicare drug
21 integrity contractor with which the Secretary
22 has entered into a contract under section 1893
23 with respect to such State a report, on a
24 monthly basis, containing information on—

1 “(i) any provider of services or sup-
2 plier described in subparagraph (A)(ii)(II)
3 that is identified by such plan sponsor dur-
4 ing the 30-day period before such report is
5 submitted; and

6 “(ii) the name and prescription
7 records of individuals described in para-
8 graph (5)(C).”.

9 (c) EXPANDING ACTIVITIES OF MEDICARE DRUG IN-
10 INTEGRITY CONTRACTORS (MEDICs).—Section 1893 of the
11 Social Security Act (42 U.S.C. 1395ddd) is amended by
12 adding at the end the following new subsection:

13 “(j) EXPANDING ACTIVITIES OF MEDICARE DRUG
14 INTEGRITY CONTRACTORS (MEDICs).—

15 “(1) ACCESS TO INFORMATION.—Under con-
16 tracts entered into under this section with Medicare
17 drug integrity contractors, the Secretary shall au-
18 thorize such contractors to directly accept prescrip-
19 tion and necessary medical records from entities
20 such as pharmacies, prescription drug plans, and
21 physicians with respect to an individual in order for
22 such contractors to provide information relevant to
23 the determination of whether such individual is an
24 at-risk beneficiary for prescription drug abuse, as
25 defined in section 1860D–4(c)(5)(C).

1 “(2) REQUIREMENT FOR ACKNOWLEDGMENT
2 OF REFERRALS.—If a PDP sponsor refers informa-
3 tion to a contractor described in paragraph (1) in
4 order for such contractor to assist in the determina-
5 tion described in such paragraph, the contractor
6 shall—

7 “(A) acknowledge to the PDP sponsor re-
8 ceipt of the referral; and

9 “(B) in the case that any PDP sponsor
10 contacts the contractor requesting to know the
11 determination by the contractor of whether or
12 not an individual has been determined to be an
13 individual described such paragraph, shall in-
14 form such PDP sponsor of such determination
15 on a date that is not later than 15 days after
16 the date on which the PDP sponsor contacts
17 the contractor.

18 “(3) MAKING DATA AVAILABLE TO OTHER
19 ENTITIESSECT.—

20 “(A) IN GENERAL.—For purposes of car-
21 rying out this subsection, subject to subpara-
22 graph (B), the Secretary shall authorize MED-
23 ICs to respond to requests for information from
24 PDP sponsors, State prescription drug moni-
25 toring programs, and other entities delegated by

1 PDP sponsors using available programs and
2 systems in the effort to prevent fraud, waste,
3 and abuse.

4 “(B) HIPAA COMPLIANT INFORMATION
5 ONLY.—Information may only be disclosed by a
6 MEDIC under subparagraph (A) if the dislo-
7 sure of such information is permitted under the
8 Federal regulations (concerning the privacy of
9 individually identifiable health information) pro-
10 mulgated under section 264(c) of the Health
11 Insurance Portability and Accountability Act of
12 1996 (42 U.S.C. 1320d–2 note).”.

13 (d) TREATMENT OF CERTAIN COMPLAINTS FOR PUR-
14 POSES OF QUALITY OR PERFORMANCE ASSESSMENT.—
15 Section 1860D–42 of the Social Security Act (42 U.S.C.
16 1395w–152) is amended by adding at the end the fol-
17 lowing new subsection:

18 “(d) TREATMENT OF CERTAIN COMPLAINTS FOR
19 PURPOSES OF QUALITY OR PERFORMANCE ASSESS-
20 MENT.—In conducting a quality or performance assess-
21 ment of a PDP sponsor, the Secretary shall develop or
22 utilize existing screening methods for reviewing and con-
23 sidering complaints that are received from enrollees in a
24 prescription drug plan offered by such PDP sponsor and
25 that are complaints regarding the lack of access by the

1 individual to prescription drugs due to a drug manage-
2 ment program for at-risk beneficiaries.”.

3 (e) GAO STUDIES AND REPORTS.—

4 (1) STUDIES.—The Comptroller General of the
5 United States shall conduct a study on each of the
6 following:

7 (A) The implementation of the amend-
8 ments made by this section.

9 (B) The effectiveness of the at-risk bene-
10 ficiaries for prescription drug abuse drug man-
11 agement programs authorized by section
12 1860D–4(c)(5) of the Social Security Act (42
13 U.S.C. 1395w–10(c)(5)), as added by sub-
14 section (a)(1), including an analysis of—

15 (i) the impediments, if any, that im-
16 pair the ability of individuals described in
17 subparagraph (C) of such section 1860D–
18 4(c)(5) to access clinically appropriate lev-
19 els of prescription drugs; and

20 (ii) the types of—

21 (I) individuals who, in the imple-
22 mentation of such section, are deter-
23 mined to be individuals described in
24 such subparagraph; and

1 (II) prescribers and pharmacies
2 that are selected under subparagraph
3 (D) of such section.

4 (2) REPORTS.—Not later than January 1,
5 2016, the Comptroller General of the United States
6 shall begin work, with respect to each study de-
7 scribed in paragraph (1), on a report that describes
8 the result of such study. Upon the completion of
9 each such report, such Comptroller General shall
10 submit the report to each of the committees de-
11 scribed in paragraph (3).

12 (3) COMMITTEES DESCRIBED.—The committees
13 described in this paragraph are the following:

14 (A) The Committee on Ways and Means of
15 the House of Representatives.

16 (B) The Committee on Energy and Com-
17 merce of the House of Representatives.

18 (C) The Committee on Finance of the Sen-
19 ate.

20 (D) The Committee on Health, Education,
21 Labor, and Pensions of the Senate.

22 (E) The Special Committee on Aging of
23 the Senate.

24 (f) EFFECTIVE DATE.—

1 (1) IN GENERAL.—The amendments made by
2 this section shall apply to prescription drug plans for
3 plan years beginning on or after January 1, 2017.

4 (2) STAKEHOLDER MEETINGS PRIOR TO EFFEC-
5 TIVE DATE.—

6 (A) IN GENERAL.—Not later than January
7 1, 2016, the Secretary shall convene stake-
8 holders, including individuals entitled to bene-
9 fits under part A of title XVIII of the Social
10 Security Act or enrolled under part B of such
11 title of such Act, advocacy groups representing
12 such individuals, clinicians, plan sponsors, and
13 entities delegated by plan sponsors, for input
14 regarding the topics described in subparagraph
15 (B).

16 (B) TOPICS DESCRIBED.— The topics de-
17 scribed in this subparagraph are the topics of—

18 (i) ensuring affordability and accessi-
19 bility to prescription drugs for enrollees in
20 prescription drug plans of PDP sponsors
21 who are at-risk beneficiaries for prescrip-
22 tion drug abuse (as defined in paragraph
23 (5)(C) of section 1860D–4(c) of the Social
24 Security Act (42 U.S.C. 1395w–10(c)));

1 (ii) the use of an expedited appeals
2 process under which such an enrollee may
3 appeal an identification of such enrollee as
4 an at-risk beneficiary for prescription drug
5 abuse under such paragraph (similar to the
6 processes established under the Medicare
7 Advantage program under part C of title
8 XVIII of the Social Security Act that allow
9 an automatic escalation to external review
10 of claims submitted under such part);

11 (iii) the types of enrollees that should
12 be treated as exempted individuals, as de-
13 scribed in clause (ii) of such paragraph;

14 (iv) the manner in which terms and
15 definitions in paragraph (5) of such section
16 1860D-4(c) should be applied, such as the
17 use of clinical appropriateness in deter-
18 mining whether an enrollee is an at-risk
19 beneficiary for prescription drug abuse as
20 defined in subparagraph (C) of such para-
21 graph (5);

22 (v) the information to be included in
23 the notices described in subparagraph (B)
24 of such section and the standardization of
25 such notices; and

1 (vi) with respect to a PDP sponsor
2 that establishes a drug management pro-
3 gram for at-risk beneficiaries under such
4 paragraph (5), the responsibilities of such
5 PDP sponsor with respect to the imple-
6 mentation of such program.

7 (C) RULEMAKING.—The Secretary shall
8 promulgate regulations based on the input
9 gathered pursuant to subparagraph (A).

10 **SEC. 13. GUIDANCE ON APPLICATION OF COMMON RULE TO**
11 **CLINICAL DATA REGISTRIES.**

12 Not later than one year after the date of the enact-
13 ment of this section, the Secretary of Health and Human
14 Services shall issue a clarification or modification with re-
15 spect to the application of subpart A of part 46 of title
16 45, Code of Federal Regulations, governing the protection
17 of human subjects in research (and commonly known as
18 the “Common Rule”), to activities, including quality im-
19 provement activities, involving clinical data registries, in-
20 cluding entities that are qualified clinical data registries
21 pursuant to section 1848(m)(3)(E) of the Social Security
22 Act (42 U.S.C. 1395w-4(m)(3)(E)).

1 **SEC. 14. ELIMINATING CERTAIN CIVIL MONEY PENALTIES;**
2 **GAINSHARING STUDY AND REPORT.**

3 (a) ELIMINATING CIVIL MONEY PENALTIES FOR IN-
4 DUCEMENTS TO PHYSICIANS TO LIMIT SERVICES THAT
5 ARE NOT MEDICALLY NECESSARY.—

6 (1) IN GENERAL.—Section 1128A(b)(1) of the
7 Social Security Act (42 U.S.C. 1320a–7a(b)(1)) is
8 amended by inserting “medically necessary” after
9 “reduce or limit”.

10 (2) EFFECTIVE DATE.—The amendment made
11 by paragraph (1) shall apply to payments made on
12 or after the date of the enactment of this Act.

13 (b) GAINSHARING STUDY AND REPORT.—Not later
14 than 12 months after the date of the enactment of this
15 Act, the Secretary of Health and Human Services, in con-
16 sultation with the Inspector General of the Department
17 of Health and Human Services, shall submit to Congress
18 a report with options for amending existing fraud and
19 abuse laws in, and regulations related to, titles XI and
20 XVIII of the Social Security Act (42 U.S.C. 301 et seq.),
21 through exceptions, safe harbors, or other narrowly tar-
22 geted provisions, to permit gainsharing arrangements that
23 otherwise would be subject to the civil money penalties de-
24 scribed in paragraphs (1) and (2) of section 1128A(b) of
25 such Act (42 U.S.C. 1320a–7a(b)), or similar arrange-
26 ments between physicians and hospitals, and that improve

1 care while reducing waste and increasing efficiency. The
2 report shall—

3 (1) consider whether such provisions should
4 apply to ownership interests, compensation arrange-
5 ments, or other relationships;

6 (2) describe how the recommendations address
7 accountability, transparency, and quality, including
8 how best to limit inducements to stint on care, dis-
9 charge patients prematurely, or otherwise reduce or
10 limit medically necessary care; and

11 (3) consider whether a portion of any savings
12 generated by such arrangements (as compared to an
13 historical benchmark or other metric specified by the
14 Secretary to determine the impact of delivery and
15 payment system changes under such title XVIII on
16 expenditures made under such title) should accrue to
17 the Medicare program under title XVIII of the So-
18 cial Security Act.

19 **SEC. 15. MODIFICATION OF MEDICARE HOME HEALTH SUR-**
20 **ETY BOND CONDITION OF PARTICIPATION**
21 **REQUIREMENT.**

22 Section 1861(o)(7) of the Social Security Act (42
23 U.S.C. 1395x(o)(7)) is amended to read as follows:

24 “(7) provides the Secretary with a surety
25 bond—

1 “(A) in a form specified by the Secretary
2 and in an amount that is not less than the min-
3 imum of \$50,000; and

4 “(B) that the Secretary determines is com-
5 mensurate with the volume of payments to the
6 home health agency; and”.

7 **SEC. 16. OVERSIGHT OF MEDICARE COVERAGE OF MANUAL**
8 **MANIPULATION OF THE SPINE TO CORRECT**
9 **SUBLUXATION.**

10 (a) IN GENERAL.—Section 1833 of the Social Secu-
11 rity Act (42 U.S.C. 1395l) is amended by adding at the
12 end the following new subsection:

13 “(z) MEDICAL REVIEW OF SPINAL SUBLUXATION
14 SERVICES.—

15 “(1) IN GENERAL.—The Secretary shall imple-
16 ment a process for the medical review (as described
17 in paragraph (2)) of treatment by a chiropractor de-
18 scribed in section 1861(r)(5) by means of manual
19 manipulation of the spine to correct a subluxation
20 (as described in such section) of an individual who
21 is enrolled under this part and apply such process to
22 such services furnished on or after January 1, 2017,
23 focusing on services such as—

1 “(A) services furnished by a such a chiro-
2 practor whose pattern of billing is aberrant
3 compared to peers; and

4 “(B) services furnished by such a chiro-
5 practor who, in a prior period, has a services
6 denial percentage in the 85th percentile or
7 greater, taking into consideration the extent
8 that service denials are overturned on appeal.

9 “(2) MEDICAL REVIEW.—

10 “(A) PRIOR AUTHORIZATION MEDICAL RE-
11 VIEW.—

12 “(i) IN GENERAL.—Subject to clause
13 (ii), the Secretary shall use prior author-
14 ization medical review for services de-
15 scribed in paragraph (1) that are furnished
16 to an individual by a chiropractor de-
17 scribed in section 1861(r)(5) that are part
18 of an episode of treatment that includes
19 more than 12 services. For purposes of the
20 preceding sentence, an episode of treat-
21 ment shall be determined by the underlying
22 cause that justifies the need for services,
23 such as a diagnosis code.

24 “(ii) ENDING APPLICATION OF PRIOR
25 AUTHORIZATION MEDICAL REVIEW.—The

1 Secretary shall end the application of prior
2 authorization medical review under clause
3 (i) to services described in paragraph (1)
4 by such a chiropractor if the Secretary de-
5 termines that the chiropractor has a low
6 denial rate under such prior authorization
7 medical review. The Secretary may subse-
8 quently reapply prior authorization medical
9 review to such chiropractor if the Secretary
10 determines it to be appropriate and the
11 chiropractor has, in the time period subse-
12 quent to the determination by the Sec-
13 retary of a low denial rate with respect to
14 the chiropractor, furnished such services
15 described in paragraph (1).

16 “(iii) EARLY REQUEST FOR PRIOR AU-
17 THORIZATION REVIEW PERMITTED.—Noth-
18 ing in this subsection shall be construed to
19 prevent such a chiropractor from request-
20 ing prior authorization for services de-
21 scribed in paragraph (1) that are to be
22 furnished to an individual before the chiro-
23 practor furnishes the twelfth such service
24 to such individual for an episode of treat-
25 ment.

1 “(B) TYPE OF REVIEW.—The Secretary
2 may use pre-payment review or post-payment
3 review of services described in section
4 1861(r)(5) that are not subject to prior author-
5 ization medical review under subparagraph (A).

6 “(C) RELATIONSHIP TO LAW ENFORCE-
7 MENT ACTIVITIES.—The Secretary may deter-
8 mine that medical review under this subsection
9 does not apply in the case where potential fraud
10 may be involved.

11 “(3) NO PAYMENT WITHOUT PRIOR AUTHORIZA-
12 TION.—With respect to a service described in para-
13 graph (1) for which prior authorization medical re-
14 view under this subsection applies, the following
15 shall apply:

16 “(A) PRIOR AUTHORIZATION DETERMINA-
17 TION.—The Secretary shall make a determina-
18 tion, prior to the service being furnished, of
19 whether the service would or would not meet
20 the applicable requirements of section
21 1862(a)(1)(A).

22 “(B) DENIAL OF PAYMENT.—Subject to
23 paragraph (5), no payment may be made under
24 this part for the service unless the Secretary
25 determines pursuant to subparagraph (A) that

1 the service would meet the applicable require-
2 ments of such section 1862(a)(1)(A).

3 “(4) SUBMISSION OF INFORMATION.—A chiro-
4 practor described in section 1861(r)(5) may submit
5 the information necessary for medical review by fax,
6 by mail, or by electronic means. The Secretary shall
7 make available the electronic means described in the
8 preceding sentence as soon as practicable.

9 “(5) TIMELINESS.—If the Secretary does not
10 make a prior authorization determination under
11 paragraph (3)(A) within 14 business days of the
12 date of the receipt of medical documentation needed
13 to make such determination, paragraph (3)(B) shall
14 not apply.

15 “(6) APPLICATION OF LIMITATION ON BENE-
16 FICIARY LIABILITY.—Where payment may not be
17 made as a result of the application of paragraph
18 (2)(B), section 1879 shall apply in the same manner
19 as such section applies to a denial that is made by
20 reason of section 1862(a)(1).

21 “(7) REVIEW BY CONTRACTORS.—The medical
22 review described in paragraph (2) may be conducted
23 by medicare administrative contractors pursuant to
24 section 1874A(a)(4)(G) or by any other contractor

1 determined appropriate by the Secretary that is not
2 a recovery audit contractor.

3 “(8) MULTIPLE SERVICES.—The Secretary
4 shall, where practicable, apply the medical review
5 under this subsection in a manner so as to allow an
6 individual described in paragraph (1) to obtain, at a
7 single time rather than on a service-by-service basis,
8 an authorization in accordance with paragraph
9 (3)(A) for multiple services.

10 “(9) CONSTRUCTION.—With respect to a serv-
11 ice described in paragraph (1) that has been af-
12 firmed by medical review under this subsection,
13 nothing in this subsection shall be construed to pre-
14 clude the subsequent denial of a claim for such serv-
15 ice that does not meet other applicable requirements
16 under this Act.

17 “(10) IMPLEMENTATION.—

18 “(A) AUTHORITY.—The Secretary may im-
19 plement the provisions of this subsection by in-
20 terim final rule with comment period.

21 “(B) ADMINISTRATION.—Chapter 35 of
22 title 44, United States Code, shall not apply to
23 medical review under this subsection.”.

24 (b) IMPROVING DOCUMENTATION OF SERVICES.—

1 (1) IN GENERAL.—The Secretary of Health and
2 Human Services shall, in consultation with stake-
3 holders (including the American Chiropractic Asso-
4 ciation) and representatives of medicare administra-
5 tive contractors (as defined in section
6 1874A(a)(3)(A) of the Social Security Act (42
7 U.S.C. 1395kk–1(a)(3)(A))), develop educational
8 and training programs to improve the ability of
9 chiropractors to provide documentation to the Sec-
10 retary of services described in section 1861(r)(5) in
11 a manner that demonstrates that such services are,
12 in accordance with section 1862(a)(1) of such Act
13 (42 U.S.C. 1395y(a)(1)), reasonable and necessary
14 for the diagnosis or treatment of illness or injury or
15 to improve the functioning of a malformed body
16 member.

17 (2) TIMING.—The Secretary shall make the
18 educational and training programs described in
19 paragraph (1) publicly available not later than Janu-
20 ary 1, 2016.

21 (3) FUNDING.—The Secretary shall use funds
22 made available under section 1893(h)(10) of the So-
23 cial Security Act (42 U.S.C. 1395ddd(h)(10)), as
24 added by section 6, to carry out this subsection.

25 (c) GAO STUDY AND REPORT.—

1 (1) STUDY.—The Comptroller General of the
2 United States shall conduct a study on the effective-
3 ness of the process for medical review of services
4 furnished as part of a treatment by means of man-
5 ual manipulation of the spine to correct a sub-
6 luxation implemented under subsection (z) of section
7 1833 of the Social Security Act (42 U.S.C. 1395l),
8 as added by subsection (a). Such study shall include
9 an analysis of—

10 (A) aggregate data on—

11 (i) the number of individuals, chiro-
12 practores, and claims for services subject to
13 such review; and

14 (ii) the number of reviews conducted
15 under such section; and

16 (B) the outcomes of such reviews.

17 (2) REPORT.—Not later than four years after
18 the date of enactment of this Act, the Comptroller
19 General shall submit to Congress a report containing
20 the results of the study conducted under paragraph
21 (1), including recommendations for such legislation
22 and administrative action with respect to the process
23 for medical review implemented under subsection (z)
24 of section 1833 of the Social Security Act (42

1 U.S.C. 1395l) as the Comptroller General deter-
2 mines appropriate.

3 **SEC. 17. LIMITING PAYMENT AMOUNT UNDER MEDICARE**
4 **PROGRAM FOR VACUUM ERECTION SYSTEMS.**

5 (a) INCLUSION IN PROGRAM.—Section 1847(a)(2) of
6 the Social Security Act (42 U.S.C. 1395w–3(a)(2)) is
7 amended by adding at the end the following new subpara-
8 graph:

9 “(D) VACUUM ERECTION SYSTEMS.—Vacu-
10 um erection systems covered as prosthetic de-
11 vices described in section 1861(s)(8) for which
12 payment would otherwise be made under section
13 1834(h).”.

14 (b) NATIONAL MAIL ORDER PROGRAM.—Section
15 1847(a)(1)(D) of the Social Security Act (42 U.S.C.
16 1395w–3(a)(1)(D)) is amended by adding at the end the
17 following new clause:

18 “(iv) NATIONAL MAIL ORDER PRO-
19 GRAM FOR VACUUM ERECTION SYSTEMS.—
20 The Secretary shall phase in a national
21 mail order program under this section for
22 vacuum erection systems described in para-
23 graph (2)(D). The first round of competi-
24 tion for such program shall occur in 2016,
25 with contracts taking effect after the com-

1 petition is completed. Chapter 35 of title
2 44, United States Code (commonly re-
3 ferred to as the ‘Paperwork Reduction Act
4 of 1995’) shall not apply to the first round
5 competition for such program.”.

6 **SEC. 18. NATIONAL EXPANSION OF PRIOR AUTHORIZATION**
7 **MODEL FOR REPETITIVE SCHEDULED NON-**
8 **EMERGENT AMBULANCE TRANSPORT.**

9 (a) INITIAL EXPANSION.—

10 (1) IN GENERAL.—In implementing the model
11 described in paragraph (2) proposed to be tested
12 under subsection (b) of section 1115A of the Social
13 Security Act (42 U.S.C. 1315a), the Secretary of
14 Health and Human Services shall revise the testing
15 under subsection (b) of such section to cover, effec-
16 tive January 1, 2016, States located in medicare ad-
17 ministrative contractor (MAC) regions L and 11
18 (consisting of Delaware, the District of Columbia,
19 Maryland, New Jersey, Pennsylvania, North Caro-
20 lina, South Carolina, West Virginia, and Virginia).

21 (2) MODEL DESCRIBED.—The model described
22 in this paragraph is the testing of a model of prior
23 authorization for repetitive scheduled non-emergent
24 ambulance transport proposed to be carried out in
25 New Jersey, Pennsylvania, and South Carolina.

1 (3) FUNDING.—The Secretary shall allocate
2 funds made available under section 1115A(f)(1)(B)
3 of the Social Security Act (42 U.S.C.
4 1315a(f)(1)(B)) to carry out this subsection.

5 (b) NATIONAL EXPANSION.—Section 1834(l) of the
6 Social Security Act (42 U.S.C. 1395m(l)) is amended by
7 adding at the end the following new paragraph:

8 “(16) PRIOR AUTHORIZATION FOR REPETITIVE
9 SCHEDULED NON-EMERGENCY AMBULANCE TRANS-
10 PORTS.—

11 “(A) IN GENERAL.—Beginning January 1,
12 2017, the Secretary shall apply the prior au-
13 thorization program described in subparagraph
14 (B) to all States.

15 “(B) PROGRAM DESCRIBED.—The prior
16 authorization program described in this sub-
17 paragraph is a prior authorization program for
18 repetitive scheduled ambulance services con-
19 sisting of non-emergency basic life support serv-
20 ices involving transport of an individual fur-
21 nished other than on an emergency basis. In
22 carrying out the program, the Secretary shall
23 determine in advance of the provision of items
24 and services related to the provision of such an
25 ambulance service whether payment for such

1 items or services may not be made because the
2 item or service is not covered or because of the
3 application of section 1862(a)(1).

4 “(C) IMPLEMENTATION.—The program de-
5 scribed in subparagraph (B) shall be imple-
6 mented in a manner that is consistent with the
7 terms and conditions for the testing of a model
8 of prior authorization for repetitive scheduled
9 non-emergent ambulance transport proposed by
10 the Centers for Medicare & Medicaid Services
11 to be implemented in New Jersey, Pennsyl-
12 vania, and South Carolina under section
13 1115A.

14 “(D) FUNDING.—The Secretary shall use
15 funds made available under section 1893(h)(10)
16 to carry out this paragraph.”.

17 **SEC. 19. REPEALING DUPLICATIVE MEDICARE SECONDARY**
18 **PAYOR PROVISION.**

19 (a) IN GENERAL.—Section 1862(b)(5) of the Social
20 Security Act (42 U.S.C. 1395y(b)(5)) is amended by in-
21 serting at the end the following new subparagraph:

22 “(E) END DATE.—The provisions of this
23 paragraph shall not apply to information re-
24 quired to be provided on or after July 1,
25 2016.”.

1 (b) EFFECTIVE DATE.—The amendment made by
2 subsection (a) shall take effect on the date of the enact-
3 ment of this Act and shall apply to information required
4 to be provided on or after January 1, 2016.

5 **SEC. 20. PLAN FOR EXPANDING DATA IN ANNUAL CERT RE-**
6 **PORT.**

7 Not later than March 25, 2015, the Secretary of
8 Health and Human Services shall submit to the Com-
9 mittee on Finance of the Senate, and to the Committees
10 on Energy and Commerce and on Ways and Means of the
11 House of Representatives—

12 (1) a plan for including, in the annual report of
13 the Comprehensive Error Rate Testing (CERT) pro-
14 gram, data on services (or groupings of services)
15 (other than medical visits) paid under the physician
16 fee schedule under section 1848 of the Social Secu-
17 rity Act (42 U.S.C. 1395w-4) where the fee sched-
18 ule amount is in excess of 250 dollars and where the
19 error rate is in excess of 20 percent; and

20 (2) to the extent practicable by such date, spe-
21 cific examples of services described in paragraph (1).

22 **SEC. 21. RULE OF CONSTRUCTION.**

23 Except as explicitly provided in this Act, nothing in
24 this Act, including the amendments made by this Act,
25 shall be construed as preventing the use of notice and com-

1 ment rulemaking in the implementation of the provisions
2 of, and the amendments made by, this Act.