

**AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO H.R. 1021
OFFERED BY MR. RYAN OF WISCONSIN**

Strike all after the enacting clause and insert the following:

1 SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

2 (a) **SHORT TITLE.**—This Act may be cited as the
3 “Protecting the Integrity of Medicare Act of 2015”.

4 (b) **TABLE OF CONTENTS.**—The table of contents for
5 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. National expansion of prior authorization model for repetitive scheduled non-emergent ambulance transport.
- Sec. 18. Repealing duplicative Medicare secondary payor provision.

Sec. 19. Plan for expanding data in annual CERT report.

Sec. 20. Removing funds for Medicare Improvement Fund added by IMPACT Act of 2014.

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

12 (3) by adding at the end the following new
13 clause:

14 “(xiii) The Secretary of Health and Human Services,
15 in consultation with the Commissioner of Social Security,
16 shall establish cost-effective procedures to ensure that a
17 Social Security account number (or derivative thereof) is
18 not displayed, coded, or embedded on the Medicare card
19 issued to an individual who is entitled to benefits under
20 part A of title XVIII or enrolled under part B of title
21 XVIII and that any other identifier displayed on such card
22 is not identifiable as a Social Security account number (or
23 derivative thereof).”.

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

6 (1) IN GENERAL.—Establish a cost-effective
7 process that involves the least amount of disruption
8 to, as well as necessary assistance for, Medicare
9 beneficiaries and health care providers, such as a
10 process that provides such beneficiaries with access
11 to assistance through a toll-free telephone number
12 and provides outreach to providers.

13 (2) CONSIDERATION OF MEDICARE BENE-
14 FICIARY IDENTIFIED.—Consider implementing a
15 process, similar to the process involving Railroad Re-
16 tirement Board beneficiaries, under which a Medi-
17 care beneficiary identifier which is not a Social Secu-
18 rity account number (or derivative thereof) is used
19 external to the Department of Health and Human
20 Services and is convertible over to a Social Security
21 account number (or derivative thereof) for use inter-
22 nal to such Department and the Social Security Ad-
23 ministration.

24 (c) FUNDING FOR IMPLEMENTATION.—For purposes
25 of implementing the provisions of and the amendments

1 made by this section, the Secretary of Health and Human
2 Services shall provide for the following transfers from the
3 Federal Hospital Insurance Trust Fund under section
4 1817 of the Social Security Act (42 U.S.C. 1395i) and
5 from the Federal Supplementary Medical Insurance Trust
6 Fund established under section 1841 of such Act (42
7 U.S.C. 1395t), in such proportions as the Secretary deter-
8 mines appropriate:

9 (1) To the Centers for Medicare & Medicaid
10 Program Management Account, transfers of the fol-
11 lowing amounts:

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

14 (B) For each of fiscal years 2016 and
15 2017, \$53,000,000, to be made available
16 through fiscal year 2018.

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

19 (2) To the Social Security Administration Limi-
20 tation on Administration Account, transfers of the
21 following amounts:

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

1 (B) For each of fiscal years 2016 and
2 2017, \$22,000,000, to be made available
3 through fiscal year 2018.

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

6 (3) To the Railroad Retirement Board Limita-
7 tion on Administration Account, the following
8 amount:

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

11 (d) EFFECTIVE DATE.—

12 (1) IN GENERAL.—Clause (xiii) of section
13 205(c)(2)(C) of the Social Security Act (42 U.S.C.
14 405(c)(2)(C)), as added by subsection (a)(3), shall
15 apply with respect to Medicare cards issued on and
16 after an effective date specified by the Secretary of
17 Health and Human Services, but in no case shall
18 such effective date be later than the date that is four
19 years after the date of the enactment of this Act.

20 (2) REISSUANCE.—The Secretary shall provide
21 for the reissuance of Medicare cards that comply
22 with the requirements of such clause not later than
23 four years after the effective date specified by the
24 Secretary under paragraph (1).

1 **SEC. 3. PREVENTING WRONGFUL MEDICARE PAYMENTS**
2 **FOR ITEMS AND SERVICES FURNISHED TO IN-**
3 **CARCERATED INDIVIDUALS, INDIVIDUALS**
4 **NOT LAWFULLY PRESENT, AND DECEASED IN-**
5 **DIVIDUALS.**

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

12 “(f) REQUIREMENT FOR THE SECRETARY TO ESTAB-
13 LISH POLICIES AND CLAIMS EDITS RELATING TO INCAR-
14 CERATED INDIVIDUALS, INDIVIDUALS NOT LAWFULLY
15 PRESENT, AND DECEASED INDIVIDUALS.—The Secretary
16 shall establish and maintain procedures, including proce-
17 dures for using claims processing edits, updating eligibility
18 information to improve provider accessibility, and con-
19 ducting recoupment activities such as through recovery
20 audit contractors, in order to ensure that payment is not
21 made under this title for items and services furnished to
22 an individual who is one of the following:

23 “(1) An individual who is incarcerated.

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

1 “(3) A deceased individual.”.

2 (b) REPORT.—Not later than 18 months after the
3 date of the enactment of this section, and periodically
4 thereafter as determined necessary by the Office of Inspec-
5 tor General of the Department of Health and Human
6 Services, such Office shall submit to Congress a report
7 on the activities described in subsection (f) of section 1874
8 of the Social Security Act (42 U.S.C. 1395kk), as added
9 by subparagraph (a), that have been conducted since such
10 date of enactment.

11 **SEC. 4. CONSIDERATION OF MEASURES REGARDING MEDI-**
12 **CARE BENEFICIARY SMART CARDS.**

13 To the extent the Secretary of Health and Human
14 Services determines that it is cost effective and techno-
15 logically viable to use electronic Medicare beneficiary and
16 provider cards (such as cards that use smart card tech-
17 nology, including an embedded and secure integrated cir-
18 cuit chip), as presented in the Government Accountability
19 Office report required by the conference report accom-
20 panying the Consolidated Appropriations Act, 2014 (Pub-
21 lic Law 113–76), the Secretary shall consider such meas-
22 ures as determined appropriate by the Secretary to imple-
23 ment such use of such cards for beneficiary and provider
24 use under title XVIII of the Social Security Act (42
25 U.S.C. 1395 et seq.). In the case that the Secretary con-

1 siders measures under the preceding sentence, the Sec-
2 retary shall submit to the Committees on Ways and Means
3 and on Energy and Commerce of the House of Represent-
4 atives, and to the Committee on Finance of the Senate,
5 a report outlining the considerations undertaken by the
6 Secretary under such sentence.

7 **SEC. 5. MODIFYING MEDICARE DURABLE MEDICAL EQUIP-**
8 **MENT FACE-TO-FACE ENCOUNTER DOCU-**
9 **MENTATION REQUIREMENT.**

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

13 (1) by striking “the physician documenting
14 that”; and

15 (2) by striking “has had a face-to-face encoun-
16 ter” and inserting “documenting such physician,
17 physician assistant, practitioner, or specialist has
18 had a face-to-face encounter”.

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

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

2 (a) MEDICARE ADMINISTRATIVE CONTRACTOR IM-
3 PROPER PAYMENT OUTREACH AND EDUCATION PRO-
4 GRAM.—

5 (1) IN GENERAL.—Section 1874A of the Social
6 Security Act (42 U.S.C. 1395kk–1) is amended—

7 (A) in subsection (a)(4)—

8 (i) by redesignating subparagraph (G)
9 as subparagraph (H); and

10 (ii) by inserting after subparagraph
11 (F) the following new subparagraph:

12 “(G) IMPROPER PAYMENT OUTREACH AND
13 EDUCATION PROGRAM.—Having in place an im-
14 proper payment outreach and education pro-
15 gram described in subsection (h).”; and

16 (B) by adding at the end the following new
17 subsection:

18 “(h) IMPROPER PAYMENT OUTREACH AND EDU-
19 CATION PROGRAM.—

20 “(1) IN GENERAL.—In order to reduce im-
21 proper payments under this title, each medicare ad-
22 ministrative contractor shall establish and have in
23 place an improper payment outreach and education
24 program under which the contractor, through out-
25 reach, education, training, and technical assistance
26 or other activities, shall provide providers of services

1 and suppliers located in the region covered by the
2 contract under this section with the information de-
3 scribed in paragraph (2). The activities described in
4 the preceding sentence shall be conducted on a reg-
5 ular basis.

6 “(2) INFORMATION TO BE PROVIDED THROUGH
7 ACTIVITIES.—The information to be provided under
8 such payment outreach and education program shall
9 include information the Secretary determines to be
10 appropriate which may include the following infor-
11 mation:

12 “(A) A list of the providers’ or suppliers’
13 most frequent and expensive payment errors
14 over the last quarter.

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

17 “(C) A notice of new topics that have been
18 approved by the Secretary for audits conducted
19 by recovery audit contractors under section
20 1893(h).

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

23 “(E) Other information determined appro-
24 priate by the Secretary.

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

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

7 “(B) Are for items and service that have
8 the greatest total dollar amount of improper
9 payments.

10 “(C) Are due to clear misapplication or
11 misinterpretation of Medicare policies.

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

14 “(E) Are due to other types of errors that
15 the Secretary determines could be prevented
16 through activities under the program.

17 “(4) INFORMATION ON IMPROPER PAYMENTS
18 FROM RECOVERY AUDIT CONTRACTORS.—

19 “(A) IN GENERAL.—In order to assist
20 medicare administrative contractors in carrying
21 out improper payment outreach and education
22 programs, the Secretary shall provide each con-
23 tractor with a complete list of the types of im-
24 proper payments identified by recovery audit
25 contractors under section 1893(h) with respect

1 to providers of services and suppliers located in
2 the region covered by the contract under this
3 section. Such information shall be provided on
4 a time frame the Secretary determines appro-
5 priate which may be on a quarterly basis.

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

9 “(i) Providers of services and sup-
10 pliers that have the highest rate of im-
11 proper payments.

12 “(ii) Providers of services and sup-
13 pliers that have the greatest total dollar
14 amounts of improper payments.

15 “(iii) Items and services furnished in
16 the region that have the highest rates of
17 improper payments.

18 “(iv) Items and services furnished in
19 the region that are responsible for the
20 greatest total dollar amount of improper
21 payments.

22 “(v) Other information the Secretary
23 determines would assist the contractor in
24 carrying out the program.

1 “(5) COMMUNICATIONS.—Communications with
2 providers of services and suppliers under an im-
3 proper payment outreach and education program are
4 subject to the standards and requirements of sub-
5 section (g).”.

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

9 (1) in paragraph (2), by inserting “or section
10 1874(h)(6)” after “paragraph (1)(C)”; and

11 (2) by adding at the end the following new
12 paragraph:

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

14 “(A) IN GENERAL.—After application of
15 paragraph (1)(C), the Secretary shall retain a
16 portion of the amounts recovered by recovery
17 audit contractors for each year under this sec-
18 tion which shall be available to the program
19 management account of the Centers for Medi-
20 care & Medicaid Services for purposes of, sub-
21 ject to subparagraph (B), carrying out sections
22 1833(z), 1834(l)(16), and 1874A(a)(4)(G), car-
23 rying out section 16(b) of the Protecting the In-
24 tegrity of Medicare Act of 2015, and imple-
25 menting strategies (such as claims processing

1 edits) to help reduce the error rate of payments
2 under this title. The amounts retained under
3 the preceding sentence shall not exceed an
4 amount equal to 15 percent of the amounts re-
5 covered under this subsection, and shall remain
6 available until expended.

7 “(B) LIMITATION.—Except for uses that
8 support claims processing (including edits) or
9 system functionality for detecting fraud,
10 amounts retained under subparagraph (A) may
11 not be used for technological-related infrastruc-
12 ture, capital investments, or information sys-
13 tems.

14 “(C) NO REDUCTION IN PAYMENTS TO RE-
15 COVERY AUDIT CONTRACTORS.—Nothing in
16 subparagraph (A) shall reduce amounts avail-
17 able for payments to recovery audit contractors
18 under this subsection.”.

19 **SEC. 7. IMPROVING SENIOR MEDICARE PATROL AND**
20 **FRAUD REPORTING REWARDS.**

21 (a) IN GENERAL.—The Secretary of Health and
22 Human Services (in this section referred to as the “Sec-
23 retary”) shall develop a plan to revise the incentive pro-
24 gram under section 203(b) of the Health Insurance Port-
25 ability and Accountability Act of 1996 (42 U.S.C. 1395b-

1 5(b)) to encourage greater participation by individuals to
2 report fraud and abuse in the Medicare program. Such
3 plan shall include recommendations for—

4 (1) ways to enhance rewards for individuals re-
5 porting under the incentive program, including re-
6 wards based on information that leads to an admin-
7 istrative action; and

8 (2) extending the incentive program to the
9 Medicaid program.

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

18 (c) SUBMISSION OF PLAN.—Not later than 180 days
19 after the date of enactment of this Act, the Secretary shall
20 submit to Congress the plan developed under subsection
21 (a).

1 **SEC. 8. REQUIRING VALID PRESCRIBER NATIONAL PRO-**
2 **VIDER IDENTIFIERS ON PHARMACY CLAIMS.**

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

6 “(4) REQUIRING VALID PRESCRIBER NATIONAL
7 PROVIDER IDENTIFIERS ON PHARMACY CLAIMS.—

8 “(A) IN GENERAL.—For plan year 2016
9 and subsequent plan years, the Secretary shall
10 require a claim for a covered part D drug for
11 a part D eligible individual enrolled in a pre-
12 scription drug plan under this part or an MA-
13 PD plan under part C to include a prescriber
14 National Provider Identifier that is determined
15 to be valid under the procedures established
16 under subparagraph (B)(i).

17 “(B) PROCEDURES.—

18 “(i) VALIDITY OF PRESCRIBER NA-
19 TIONAL PROVIDER IDENTIFIERS.—The
20 Secretary, in consultation with appropriate
21 stakeholders, shall establish procedures for
22 determining the validity of prescriber Na-
23 tional Provider Identifiers under subpara-
24 graph (A).

25 “(ii) INFORMING BENEFICIARIES OF
26 REASON FOR DENIAL.—The Secretary shall

1 establish procedures to ensure that, in the
2 case that a claim for a covered part D
3 drug of an individual described in
4 subparagraph (A) is denied because the
5 claim does not meet the requirements of
6 this paragraph, the individual is properly
7 informed at the point of service of the rea-
8 son for the denial.

9 “(C) REPORT.—Not later than January 1,
10 2018, the Inspector General of the Department
11 of Health and Human Services shall submit to
12 Congress a report on the effectiveness of the
13 procedures established under subparagraph
14 (B)(i).”.

15 **SEC. 9. OPTION TO RECEIVE MEDICARE SUMMARY NOTICE**
16 **ELECTRONICALLY.**

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

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

21 “(1) ELECTRONIC OPTION BEGINNING IN
22 2016.—Subject to paragraph (2), for statements de-
23 scribed in subsection (a) that are furnished for a pe-
24 riod in 2016 or a subsequent year, in the case that
25 an individual described in subsection (a) elects, in

1 accordance with such form, manner, and time speci-
2 fied by the Secretary, to receive such statement in
3 an electronic format, such statement shall be fur-
4 nished to such individual for each period subsequent
5 to such election in such a format and shall not be
6 mailed to the individual.

7 “(2) LIMITATION ON REVOCATION OPTION.—

8 “(A) IN GENERAL.—Subject to subpara-
9 graph (B), the Secretary may determine a max-
10 imum number of elections described in para-
11 graph (1) by an individual that may be revoked
12 by the individual.

13 “(B) MINIMUM OF ONE REVOCATION OP-
14 TION.—In no case may the Secretary determine
15 a maximum number under subparagraph (A)
16 that is less than one.

17 “(3) NOTIFICATION.—The Secretary shall en-
18 sure that, in the most cost effective manner and be-
19 ginning January 1, 2017, a clear notification of the
20 option to elect to receive statements described in
21 subsection (a) in an electronic format is made avail-
22 able, such as through the notices distributed under
23 section 1804, to individuals described in subsection
24 (a).”.

1 (b) ENCOURAGED EXPANSION OF ELECTRONIC
2 STATEMENTS.—To the extent to which the Secretary of
3 Health and Human Services determines appropriate, the
4 Secretary shall—

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

12 (2) provide such Medicare Summary Notice and
13 any such other statements and notifications on a
14 more frequent basis than is otherwise required under
15 such title.

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

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

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

24 (c) CONTRACTOR PERFORMANCE TRANSPARENCY.—
25 Section 1874A(b)(3)(A) of the Social Security Act (42

1 U.S.C. 1395kk–1(b)(3)(A)) is amended by adding at the
2 end the following new clause:

3 “(iv) CONTRACTOR PERFORMANCE
4 TRANSPARENCY.—To the extent possible
5 without compromising the process for en-
6 tering into and renewing contracts with
7 medicare administrative contractors under
8 this section, the Secretary shall make
9 available to the public the performance of
10 each medicare administrative contractor
11 with respect to such performance require-
12 ments and measurement standards.”.

13 **SEC. 11. STUDY ON PATHWAY FOR INCENTIVES TO STATES**
14 **FOR STATE PARTICIPATION IN MEDICAID**
15 **DATA MATCH PROGRAM.**

16 Section 1893(g) of the Social Security Act (42 U.S.C.
17 1395ddd(g)) is amended by adding at the end the fol-
18 lowing new paragraph:

19 “(3) INCENTIVES FOR STATES.—The Secretary
20 shall study and, as appropriate, may specify incen-
21 tives for States to work with the Secretary for the
22 purposes described in paragraph (1)(A)(ii). The ap-
23 plication of the previous sentence may include use of
24 the waiver authority described in paragraph (2).”.

1 **SEC. 12. PROGRAMS TO PREVENT PRESCRIPTION DRUG**
2 **ABUSE UNDER MEDICARE PART D.**

3 (a) DRUG MANAGEMENT PROGRAM FOR AT-RISK
4 BENEFICIARIES.—

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

9 “(5) DRUG MANAGEMENT PROGRAM FOR AT-
10 RISK BENEFICIARIES.—

11 “(A) AUTHORITY TO ESTABLISH.—A PDP
12 sponsor may establish a drug management pro-
13 gram for at-risk beneficiaries under which, sub-
14 ject to subparagraph (B), the PDP sponsor
15 may, in the case of an at-risk beneficiary for
16 prescription drug abuse who is an enrollee in a
17 prescription drug plan of such PDP sponsor,
18 limit such beneficiary’s access to coverage for
19 frequently abused drugs under such plan to fre-
20 quently abused drugs that are prescribed for
21 such beneficiary by a prescriber selected under
22 subparagraph (D), and dispensed for such bene-
23 ficiary by a pharmacy selected under such sub-
24 paragraph.

25 “(B) REQUIREMENT FOR NOTICES.—

1 “(i) IN GENERAL.—A PDP sponsor
2 may not limit the access of an at-risk ben-
3 eficiary for prescription drug abuse to cov-
4 erage for frequently abused drugs under a
5 prescription drug plan until such spon-
6 sor—

7 “(I) provides to the beneficiary
8 an initial notice described in clause
9 (ii) and a second notice described in
10 clause (iii); and

11 “(II) verifies with the providers
12 of the beneficiary that the beneficiary
13 is an at-risk beneficiary for prescrip-
14 tion drug abuse.

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

18 “(I) notice that the PDP sponsor
19 has identified the beneficiary as po-
20 tentially being an at-risk beneficiary
21 for prescription drug abuse;

22 “(II) information describing all
23 State and Federal public health re-
24 sources that are designed to address
25 prescription drug abuse to which the

1 beneficiary has access, including men-
2 tal health services and other coun-
3 seling services;

4 “(III) notice of, and information
5 about, the right of the beneficiary to
6 appeal such identification under sub-
7 section (h) and the option of an auto-
8 matic escalation to external review;

9 “(IV) a request for the bene-
10 ficiary to submit to the PDP sponsor
11 preferences for which prescribers and
12 pharmacies the beneficiary would pre-
13 fer the PDP sponsor to select under
14 subparagraph (D) in the case that the
15 beneficiary is identified as an at-risk
16 beneficiary for prescription drug
17 abuse as described in clause (iii)(I);

18 “(V) an explanation of the mean-
19 ing and consequences of the identi-
20 fication of the beneficiary as poten-
21 tially being an at-risk beneficiary for
22 prescription drug abuse, including an
23 explanation of the drug management
24 program established by the PDP

1 sponsor pursuant to subparagraph
2 (A);

3 “(VI) clear instructions that ex-
4 plain how the beneficiary can contact
5 the PDP sponsor in order to submit
6 to the PDP sponsor the preferences
7 described in subclause (IV) and any
8 other communications relating to the
9 drug management program for at-risk
10 beneficiaries established by the PDP
11 sponsor; and

12 “(VII) contact information for
13 other organizations that can provide
14 the beneficiary with assistance regard-
15 ing such drug management program
16 (similar to the information provided
17 by the Secretary in other standardized
18 notices provided to part D eligible in-
19 dividuals enrolled in prescription drug
20 plans under this part).

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

24 “(I) that the PDP sponsor has
25 identified the beneficiary as an at-risk

1 beneficiary for prescription drug
2 abuse;

3 “(II) that such beneficiary is
4 subject to the requirements of the
5 drug management program for at-risk
6 beneficiaries established by such PDP
7 sponsor for such plan;

8 “(III) of the prescriber and phar-
9 macy selected for such individual
10 under subparagraph (D);

11 “(IV) of, and information about,
12 the beneficiary’s right to appeal such
13 identification under subsection (h)
14 and the option of an automatic esca-
15 lation to external review;

16 “(V) that the beneficiary can, in
17 the case that the beneficiary has not
18 previously submitted to the PDP
19 sponsor preferences for which pre-
20 scribers and pharmacies the bene-
21 ficiary would prefer the PDP sponsor
22 select under subparagraph (D), sub-
23 mit such preferences to the PDP
24 sponsor; and

1 “(VI) that includes clear instruc-
2 tions that explain how the beneficiary
3 can contact the PDP sponsor.

4 “(iv) TIMING OF NOTICES.—

5 “(I) IN GENERAL.—Subject to
6 subclause (II), a second notice de-
7 scribed in clause (iii) shall be provided
8 to the beneficiary on a date that is
9 not less than 60 days after an initial
10 notice described in clause (ii) is pro-
11 vided to the beneficiary.

12 “(II) EXCEPTION.—In the case
13 that the PDP sponsor, in conjunction
14 with the Secretary, determines that
15 concerns identified through rule-
16 making by the Secretary regarding
17 the health or safety of the beneficiary
18 or regarding significant drug diversion
19 activities require the PDP sponsor to
20 provide a second notice described in
21 clause (iii) to the beneficiary on a
22 date that is earlier than the date de-
23 scribed in subclause (II), the PDP
24 sponsor may provide such second no-
25 tice on such earlier date.

1 “(C) AT-RISK BENEFICIARY FOR PRE-
2 SCRIPTION DRUG ABUSE.—

3 “(i) IN GENERAL.—For purposes of
4 this paragraph, the term ‘at-risk bene-
5 ficiary for prescription drug abuse’ means
6 a part D eligible individual who is not an
7 exempted individual described in clause (ii)
8 and—

9 “(I) who is identified through the
10 use of clinical guidelines developed by
11 the Secretary in consultation with
12 PDP sponsors and other stakeholders
13 described in section 12(f)(2)(A) of the
14 Protecting the Integrity of Medicare
15 Act of 2015; or

16 “(II) with respect to whom the
17 PDP sponsor of a prescription drug
18 plan, upon enrolling such individual in
19 such plan, received notice from the
20 Secretary that such individual was
21 identified under this paragraph to be
22 an at-risk beneficiary for prescription
23 drug abuse under the prescription
24 drug plan in which such individual
25 was most recently previously enrolled

1 and such identification has not been
2 terminated under subparagraph (F).

3 “(ii) EXEMPTED INDIVIDUAL DE-
4 SCRIBED.—An exempted individual de-
5 scribed in this clause is an individual
6 who—

7 “(I) receives hospice care under
8 this title; or

9 “(II) the Secretary elects to treat
10 as an exempted individual for pur-
11 poses of clause (i).

12 “(D) SELECTION OF PRESCRIBERS.—

13 “(i) IN GENERAL.—With respect to
14 each at-risk beneficiary for prescription
15 drug abuse enrolled in a prescription drug
16 plan offered by such sponsor, a PDP spon-
17 sor shall, based on the preferences sub-
18 mitted to the PDP sponsor by the bene-
19 ficiary pursuant to clauses (ii)(IV) and
20 (iii)(V) of subparagraph (B), select—

21 “(I) one or more individuals who
22 are authorized to prescribe frequently
23 abused drugs (referred to in this
24 paragraph as ‘prescribers’) who may

1 write prescriptions for such drugs for
2 such beneficiary; and

3 “(II) one or more pharmacies
4 that may dispense such drugs to such
5 beneficiary.

6 “(ii) REASONABLE ACCESS.—In mak-
7 ing the selection under this subparagraph,
8 a PDP sponsor shall ensure that the bene-
9 ficiary continues to have reasonable access
10 to drugs described in subparagraph (G),
11 taking into account geographic location,
12 beneficiary preference, impact on cost-
13 sharing, and reasonable travel time.

14 “(iii) BENEFICIARY PREFERENCES.—

15 “(I) IN GENERAL.—If an at-risk
16 beneficiary for prescription drug
17 abuse submits preferences for which
18 in-network prescribers and pharmacies
19 the beneficiary would prefer the PDP
20 sponsor select in response to a notice
21 under subparagraph (B), the PDP
22 sponsor shall—

23 “(aa) review such pref-
24 erences;

1 “(bb) select or change the
2 selection of a prescriber or phar-
3 macy for the beneficiary based on
4 such preferences; and

5 “(cc) inform the beneficiary
6 of such selection or change of se-
7 lection.

8 “(II) EXCEPTION.—In the case
9 that the PDP sponsor determines that
10 a change to the selection of a pre-
11 scriber or pharmacy under item (bb)
12 by the PDP sponsor is contributing or
13 would contribute to prescription drug
14 abuse or drug diversion by the bene-
15 ficiary, the PDP sponsor may change
16 the selection of a prescriber or phar-
17 macy for the beneficiary without re-
18 gard to the preferences of the bene-
19 ficiary described in subclause (I).

20 “(iv) CONFIRMATION.—Before select-
21 ing a prescriber or pharmacy under this
22 subparagraph, a PDP sponsor must re-
23 quest and receive confirmation from the
24 prescriber or pharmacy acknowledging and
25 accepting that the beneficiary involved is in

1 the drug management program for at-risk
2 beneficiaries.

3 “(E) TERMINATIONS AND APPEALS.—The
4 identification of an individual as an at-risk ben-
5 eficiary for prescription drug abuse under this
6 paragraph, a coverage determination made
7 under a drug management program for at-risk
8 beneficiaries, and the selection of a prescriber
9 or pharmacy under subparagraph (D) with re-
10 spect to such individual shall be subject to re-
11 consideration and appeal under subsection (h)
12 and the option of an automatic escalation to ex-
13 ternal review to the extent provided by the Sec-
14 retary.

15 “(F) TERMINATION OF IDENTIFICATION.—
16 “(i) IN GENERAL.—The Secretary
17 shall develop standards for the termination
18 of identification of an individual as an at-
19 risk beneficiary for prescription drug abuse
20 under this paragraph. Under such stand-
21 ards such identification shall terminate as
22 of the earlier of—

23 “(I) the date the individual dem-
24 onstrates that the individual is no
25 longer likely, in the absence of the re-

1 strictions under this paragraph, to be
2 an at-risk beneficiary for prescription
3 drug abuse described in subparagraph
4 (C)(i); or

5 “(II) the end of such maximum
6 period of identification as the Sec-
7 retary may specify.

8 “(ii) RULE OF CONSTRUCTION.—
9 Nothing in clause (i) shall be construed as
10 preventing a plan from identifying an indi-
11 vidual as an at-risk beneficiary for pre-
12 scription drug abuse under subparagraph
13 (C)(i) after such termination on the basis
14 of additional information on drug use oc-
15 curring after the date of notice of such ter-
16 mination.

17 “(G) FREQUENTLY ABUSED DRUG.—For
18 purposes of this subsection, the term ‘frequently
19 abused drug’ means a drug that is determined
20 by the Secretary to be frequently abused or di-
21 verted and that is—

22 “(i) a Controlled Drug Substance in
23 Schedule CII; or

24 “(ii) within the same class or category
25 of drugs as a Controlled Drug Substance

1 in Schedule CII, as determined through
2 notice and comment rulemaking.

3 “(H) DATA DISCLOSURE.—In the case of
4 an at-risk beneficiary for prescription drug
5 abuse whose access to coverage for frequently
6 abused drugs under a prescription drug plan
7 has been limited by a PDP sponsor under this
8 paragraph, such PDP sponsor shall disclose
9 data, including any necessary individually iden-
10 tifiable health information, in a form and man-
11 ner specified by the Secretary, about the deci-
12 sion to impose such limitations and the limita-
13 tions imposed by the sponsor under this part.

14 “(I) EDUCATION.—The Secretary shall
15 provide education to enrollees in prescription
16 drug plans of PDP sponsors and providers re-
17 garding the drug management program for at-
18 risk beneficiaries described in this paragraph,
19 including education—

20 “(i) provided by medicare administra-
21 tive contractors through the improper pay-
22 ment outreach and education program de-
23 scribed in section 1874A(h); and

24 “(ii) through current education efforts
25 (such as State health insurance assistance

1 programs described in subsection (a)(1)(A)
2 of section 119 of the Medicare Improve-
3 ments for Patients and Providers Act of
4 2008 (42 U.S.C. 1395b-3 note)) and ma-
5 terials directed toward such enrollees.”.

6 (2) INFORMATION FOR CONSUMERS.—Section
7 1860D-4(a)(1)(B) of the Social Security Act (42
8 U.S.C. 1395w-104(a)(1)(B)) is amended by adding
9 at the end the following:

10 “(v) The drug management program
11 for at-risk beneficiaries under subsection
12 (c)(5).”.

13 (b) UTILIZATION MANAGEMENT PROGRAMS.—Sec-
14 tion 1860D-4(c) of the Social Security Act (42 U.S.C.
15 1395w-104(c)), as amended by subsection (a) and section
16 8, is further amended—

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

19 “(E) A utilization management tool to pre-
20 vent drug abuse (as described in paragraph
21 (6)(A)).”; and

22 (2) by adding at the end the following new
23 paragraph:

24 “(6) UTILIZATION MANAGEMENT TOOL TO PRE-
25 VENT DRUG ABUSE.—

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

3 “(i) A utilization tool designed to pre-
4 vent the abuse of frequently abused drugs
5 by individuals and to prevent the diversion
6 of such drugs at pharmacies.

7 “(ii) Retrospective utilization review
8 to identify—

9 “(I) individuals that receive fre-
10 quently abused drugs at a frequency
11 or in amounts that are not clinically
12 appropriate; and

13 “(II) providers of services or sup-
14 pliers that may facilitate the abuse or
15 diversion of frequently abused drugs
16 by beneficiaries.

17 “(iii) Consultation with the Con-
18 tractor described in subparagraph (B) to
19 verify if an individual enrolling in a pre-
20 scription drug plan offered by a PDP
21 sponsor has been previously identified by
22 another PDP sponsor as an individual de-
23 scribed in clause (ii)(I).

24 “(B) REPORTING.—A PDP sponsor offer-
25 ing a prescription drug plan in a State shall

1 submit to the Secretary and the Medicare drug
2 integrity contractor with which the Secretary
3 has entered into a contract under section 1893
4 with respect to such State a report, on a
5 monthly basis, containing information on—

6 “(i) any provider of services or sup-
7 plier described in subparagraph (A)(ii)(II)
8 that is identified by such plan sponsor dur-
9 ing the 30-day period before such report is
10 submitted; and

11 “(ii) the name and prescription
12 records of individuals described in para-
13 graph (5)(C).”.

14 (c) EXPANDING ACTIVITIES OF MEDICARE DRUG IN-
15 TEGRITY CONTRACTORS (MEDICs).—Section 1893 of the
16 Social Security Act (42 U.S.C. 1395ddd) is amended by
17 adding at the end the following new subsection:

18 “(j) EXPANDING ACTIVITIES OF MEDICARE DRUG
19 INTEGRITY CONTRACTORS (MEDICs).—

20 “(1) ACCESS TO INFORMATION.—Under con-
21 tracts entered into under this section with Medicare
22 drug integrity contractors, the Secretary shall au-
23 thorize such contractors to directly accept prescrip-
24 tion and necessary medical records from entities
25 such as pharmacies, prescription drug plans, and

1 physicians with respect to an individual in order for
2 such contractors to provide information relevant to
3 the determination of whether such individual is an
4 at-risk beneficiary for prescription drug abuse, as
5 defined in section 1860D-4(c)(5)(C).

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

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

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

23 “(3) MAKING DATA AVAILABLE TO OTHER EN-
24 TITIES.—

1 “(A) IN GENERAL.—For purposes of car-
2 rying out this subsection, subject to subpara-
3 graph (B), the Secretary shall authorize MED-
4 ICs to respond to requests for information from
5 PDP sponsors, State prescription drug moni-
6 toring programs, and other entities delegated by
7 PDP sponsors using available programs and
8 systems in the effort to prevent fraud, waste,
9 and abuse.

10 “(B) HIPAA COMPLIANT INFORMATION
11 ONLY.—Information may only be disclosed by a
12 MEDIC under subparagraph (A) if the diselo-
13 sure of such information is permitted under the
14 Federal regulations (concerning the privacy of
15 individually identifiable health information) pro-
16 mulgated under section 264(c) of the Health
17 Insurance Portability and Accountability Act of
18 1996 (42 U.S.C. 1320d–2 note).”.

19 (d) TREATMENT OF CERTAIN COMPLAINTS FOR PUR-
20 POSES OF QUALITY OR PERFORMANCE ASSESSMENT.—
21 Section 1860D–42 of the Social Security Act (42 U.S.C.
22 1395w–152) is amended by adding at the end the fol-
23 lowing new subsection:

24 “(d) TREATMENT OF CERTAIN COMPLAINTS FOR
25 PURPOSES OF QUALITY OR PERFORMANCE ASSESS-

1 MENT.—In conducting a quality or performance assess-
2 ment of a PDP sponsor, the Secretary shall develop or
3 utilize existing screening methods for reviewing and con-
4 sidering complaints that are received from enrollees in a
5 prescription drug plan offered by such PDP sponsor and
6 that are complaints regarding the lack of access by the
7 individual to prescription drugs due to a drug manage-
8 ment program for at-risk beneficiaries.”.

9 (e) GAO STUDIES AND REPORTS.—

10 (1) STUDIES.—The Comptroller General of the
11 United States shall conduct a study on each of the
12 following:

13 (A) The implementation of the amend-
14 ments made by this section.

15 (B) The effectiveness of the at-risk bene-
16 ficiaries for prescription drug abuse drug man-
17 agement programs authorized by section
18 1860D–4(c)(5) of the Social Security Act (42
19 U.S.C. 1395w–10(c)(5)), as added by sub-
20 section (a)(1), including an analysis of—

21 (i) the impediments, if any, that im-
22 pair the ability of individuals described in
23 subparagraph (C) of such section 1860D–
24 4(c)(5) to access clinically appropriate lev-
25 els of prescription drugs; and

- 1 (ii) the types of—
- 2 (I) individuals who, in the imple-
- 3 mentation of such section, are deter-
- 4 mined to be individuals described in
- 5 such subparagraph; and
- 6 (II) prescribers and pharmacies
- 7 that are selected under subparagraph
- 8 (D) of such section.

9 (2) REPORTS.—Not later than January 1,

10 2016, the Comptroller General of the United States

11 shall begin work, with respect to each study de-

12 scribed in paragraph (1), on a report that describes

13 the result of such study. Upon the completion of

14 each such report, such Comptroller General shall

15 submit the report to each of the committees de-

16 scribed in paragraph (3).

17 (3) COMMITTEES DESCRIBED.—The committees

18 described in this paragraph are the following:

19 (A) The Committee on Ways and Means of

20 the House of Representatives.

21 (B) The Committee on Energy and Com-

22 merce of the House of Representatives.

23 (C) The Committee on Finance of the Sen-

24 ate.

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

3 (E) The Special Committee on Aging of
4 the Senate.

5 (f) EFFECTIVE DATE.—

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

9 (2) STAKEHOLDER MEETINGS PRIOR TO EFFEC-
10 TIVE DATE.—

11 (A) IN GENERAL.—Not later than January
12 1, 2016, the Secretary shall convene stake-
13 holders, including individuals entitled to bene-
14 fits under part A of title XVIII of the Social
15 Security Act or enrolled under part B of such
16 title of such Act, advocacy groups representing
17 such individuals, clinicians, plan sponsors, enti-
18 ties delegated by plan sponsors, and biopharma-
19 ceutical manufacturers for input regarding the
20 topics described in subparagraph (B).

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

23 (i) the impact on cost-sharing and en-
24 suring accessibility to prescription drugs
25 for enrollees in prescription drug plans of

1 PDP sponsors who are at-risk beneficiaries
2 for prescription drug abuse (as defined in
3 paragraph (5)(C) of section 1860D-4(c) of
4 the Social Security Act (42 U.S.C. 1395w-
5 10(c)));

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

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

19 (iv) the manner in which terms and
20 definitions in paragraph (5) of such section
21 1860D-4(c) should be applied, such as the
22 use of clinical appropriateness in deter-
23 mining whether an enrollee is an at-risk
24 beneficiary for prescription drug abuse as

1 defined in subparagraph (C) of such para-
2 graph (5);

3 (v) the information to be included in
4 the notices described in subparagraph (B)
5 of such section and the standardization of
6 such notices; and

7 (vi) with respect to a PDP sponsor
8 that establishes a drug management pro-
9 gram for at-risk beneficiaries under such
10 paragraph (5), the responsibilities of such
11 PDP sponsor with respect to the imple-
12 mentation of such program.

13 (g) RULEMAKING.—The Secretary shall promulgate
14 regulations based on the input gathered pursuant to sub-
15 section (f)(2)(A).

16 **SEC. 13. GUIDANCE ON APPLICATION OF COMMON RULE TO**
17 **CLINICAL DATA REGISTRIES.**

18 Not later than one year after the date of the enact-
19 ment of this section, the Secretary of Health and Human
20 Services shall issue a clarification or modification with re-
21 spect to the application of subpart A of part 46 of title
22 45, Code of Federal Regulations, governing the protection
23 of human subjects in research (and commonly known as
24 the “Common Rule”), to activities, including quality im-
25 provement activities, involving clinical data registries, in-

1 cluding entities that are qualified clinical data registries
2 pursuant to section 1848(m)(3)(E) of the Social Security
3 Act (42 U.S.C. 1395w-4(m)(3)(E)).

4 **SEC. 14. ELIMINATING CERTAIN CIVIL MONEY PENALTIES;**
5 **GAINSHARING STUDY AND REPORT.**

6 (a) **ELIMINATING CIVIL MONEY PENALTIES FOR IN-**
7 **DUCEMENTS TO PHYSICIANS TO LIMIT SERVICES THAT**
8 **ARE NOT MEDICALLY NECESSARY.—**

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

13 (2) **EFFECTIVE DATE.—**The amendment made
14 by paragraph (1) shall apply to payments made on
15 or after the date of the enactment of this Act.

16 (b) **GAINSHARING STUDY AND REPORT.—**Not later
17 than 12 months after the date of the enactment of this
18 Act, the Secretary of Health and Human Services, in con-
19 sultation with the Inspector General of the Department
20 of Health and Human Services, shall submit to Congress
21 a report with options for amending existing fraud and
22 abuse laws in, and regulations related to, titles XI and
23 XVIII of the Social Security Act (42 U.S.C. 301 et seq.),
24 through exceptions, safe harbors, or other narrowly tar-
25 geted provisions, to permit gainsharing arrangements that

1 otherwise would be subject to the civil money penalties de-
2 scribed in paragraphs (1) and (2) of section 1128A(b) of
3 such Act (42 U.S.C. 1320a–7a(b)), or similar arrange-
4 ments between physicians and hospitals, and that improve
5 care while reducing waste and increasing efficiency. The
6 report shall—

7 (1) consider whether such provisions should
8 apply to ownership interests, compensation arrange-
9 ments, or other relationships;

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

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

1 **SEC. 15. MODIFICATION OF MEDICARE HOME HEALTH SUR-**
2 **ETY BOND CONDITION OF PARTICIPATION**
3 **REQUIREMENT.**

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

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

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

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

14 **SEC. 16. OVERSIGHT OF MEDICARE COVERAGE OF MANUAL**
15 **MANIPULATION OF THE SPINE TO CORRECT**
16 **SUBLUXATION.**

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

20 “(z) MEDICAL REVIEW OF SPINAL SUBLUXATION
21 SERVICES.—

22 “(1) IN GENERAL.—The Secretary shall imple-
23 ment a process for the medical review (as described
24 in paragraph (2)) of treatment by a chiropractor de-
25 scribed in section 1861(r)(5) by means of manual
26 manipulation of the spine to correct a subluxation

1 (as described in such section) of an individual who
2 is enrolled under this part and apply such process to
3 such services furnished on or after January 1, 2017,
4 focusing on services such as—

5 “(A) services furnished by a such a chiro-
6 practor whose pattern of billing is aberrant
7 compared to peers; and

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

13 “(2) MEDICAL REVIEW.—

14 “(A) PRIOR AUTHORIZATION MEDICAL RE-
15 VIEW.—

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

1 cause that justifies the need for services,
2 such as a diagnosis code.

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

20 “(iii) EARLY REQUEST FOR PRIOR AU-
21 THORIZATION REVIEW PERMITTED.—Noth-
22 ing in this subsection shall be construed to
23 prevent such a chiropractor from request-
24 ing prior authorization for services de-
25 scribed in paragraph (1) that are to be

1 furnished to an individual before the chiro-
2 practor furnishes the twelfth such service
3 to such individual for an episode of treat-
4 ment.

5 “(B) TYPE OF REVIEW.—The Secretary
6 may use pre-payment review or post-payment
7 review of services described in section
8 1861(r)(5) that are not subject to prior author-
9 ization medical review under subparagraph (A).

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

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

20 “(A) PRIOR AUTHORIZATION DETERMINA-
21 TION.—The Secretary shall make a determina-
22 tion, prior to the service being furnished, of
23 whether the service would or would not meet
24 the applicable requirements of section
25 1862(a)(1)(A).

1 “(B) DENIAL OF PAYMENT.—Subject to
2 paragraph (5), no payment may be made under
3 this part for the service unless the Secretary
4 determines pursuant to subparagraph (A) that
5 the service would meet the applicable require-
6 ments of such section 1862(a)(1)(A).

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

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

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

1 “(7) REVIEW BY CONTRACTORS.—The medical
2 review described in paragraph (2) may be conducted
3 by medicare administrative contractors pursuant to
4 section 1874A(a)(4)(G) or by any other contractor
5 determined appropriate by the Secretary that is not
6 a recovery audit contractor.

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

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

21 “(10) IMPLEMENTATION.—

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

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

4 (b) IMPROVING DOCUMENTATION OF SERVICES.—

5 (1) IN GENERAL.—The Secretary of Health and
6 Human Services shall, in consultation with stake-
7 holders (including the American Chiropractic Asso-
8 ciation) and representatives of medicare administra-
9 tive contractors (as defined in section
10 1874A(a)(3)(A) of the Social Security Act (42
11 U.S.C. 1395kk–1(a)(3)(A))), develop educational
12 and training programs to improve the ability of
13 chiropractors to provide documentation to the Sec-
14 retary of services described in section 1861(r)(5) in
15 a manner that demonstrates that such services are,
16 in accordance with section 1862(a)(1) of such Act
17 (42 U.S.C. 1395y(a)(1)), reasonable and necessary
18 for the diagnosis or treatment of illness or injury or
19 to improve the functioning of a malformed body
20 member.

21 (2) TIMING.—The Secretary shall make the
22 educational and training programs described in
23 paragraph (1) publicly available not later than Janu-
24 ary 1, 2016.

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

5 (c) GAO STUDY AND REPORT.—

6 (1) STUDY.—The Comptroller General of the
7 United States shall conduct a study on the effective-
8 ness of the process for medical review of services
9 furnished as part of a treatment by means of man-
10 ual manipulation of the spine to correct a sub-
11 luxation implemented under subsection (z) of section
12 1833 of the Social Security Act (42 U.S.C. 1395l),
13 as added by subsection (a). Such study shall include
14 an analysis of—

15 (A) aggregate data on—

16 (i) the number of individuals, chiro-
17 practores, and claims for services subject to
18 such review; and

19 (ii) the number of reviews conducted
20 under such section; and

21 (B) the outcomes of such reviews.

22 (2) REPORT.—Not later than four years after
23 the date of enactment of this Act, the Comptroller
24 General shall submit to Congress a report containing
25 the results of the study conducted under paragraph

1 (1), including recommendations for such legislation
2 and administrative action with respect to the process
3 for medical review implemented under subsection (z)
4 of section 1833 of the Social Security Act (42
5 U.S.C. 1395l) as the Comptroller General deter-
6 mines appropriate.

7 **SEC. 17. NATIONAL EXPANSION OF PRIOR AUTHORIZATION**
8 **MODEL FOR REPETITIVE SCHEDULED NON-**
9 **EMERGENT AMBULANCE TRANSPORT.**

10 (a) INITIAL EXPANSION.—

11 (1) IN GENERAL.—In implementing the model
12 described in paragraph (2) proposed to be tested
13 under subsection (b) of section 1115A of the Social
14 Security Act (42 U.S.C. 1315a), the Secretary of
15 Health and Human Services shall revise the testing
16 under subsection (b) of such section to cover, effec-
17 tive not later than January 1, 2016, States located
18 in medicare administrative contractor (MAC) regions
19 L and 11 (consisting of Delaware, the District of
20 Columbia, Maryland, New Jersey, Pennsylvania,
21 North Carolina, South Carolina, West Virginia, and
22 Virginia).

23 (2) MODEL DESCRIBED.—The model described
24 in this paragraph is the testing of a model of prior
25 authorization for repetitive scheduled non-emergent

1 ambulance transport proposed to be carried out in
2 New Jersey, Pennsylvania, and South Carolina.

3 (3) FUNDING.—The Secretary shall allocate
4 funds made available under section 1115A(f)(1)(B)
5 of the Social Security Act (42 U.S.C.
6 1315a(f)(1)(B)) to carry out this subsection.

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

10 “(16) PRIOR AUTHORIZATION FOR REPETITIVE
11 SCHEDULED NON-EMERGENT AMBULANCE TRANS-
12 PORTS.—

13 “(A) IN GENERAL.—Beginning January 1,
14 2017, if the expansion to all States of the
15 model of prior authorization described in para-
16 graph (2) of section 18(a) of the Protecting the
17 Integrity of Medicare Act of 2015 meets the re-
18 quirements described in paragraphs (1) through
19 (3) of section 1115A(c), then the Secretary
20 shall expand such model to all States.

21 “(B) FUNDING.—The Secretary shall use
22 funds made available under section 1893(h)(10)
23 to carry out this paragraph.

24 “(C) CLARIFICATION REGARDING BUDGET
25 NEUTRALITY.—Nothing in this paragraph may

1 be construed to limit or modify the application
2 of section 1115A(b)(3)(B) to models described
3 in such section, including with respect to the
4 model described in subparagraph (A) and ex-
5 panded beginning on January 1, 2017, under
6 such subparagraph.”.

7 **SEC. 18. REPEALING DUPLICATIVE MEDICARE SECONDARY**
8 **PAYOR PROVISION.**

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

12 “(E) END DATE.—The provisions of this
13 paragraph shall not apply to information re-
14 quired to be provided on or after July 1,
15 2016.”.

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

20 **SEC. 19. PLAN FOR EXPANDING DATA IN ANNUAL CERT RE-**
21 **PORT.**

22 Not later than June 30, 2015, the Secretary of
23 Health and Human Services shall submit to the Com-
24 mittee on Finance of the Senate, and to the Committees

1 on Energy and Commerce and on Ways and Means of the
2 House of Representatives—

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

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

13 **SEC. 20. REMOVING FUNDS FOR MEDICARE IMPROVEMENT**

14 **FUND ADDED BY IMPACT ACT OF 2014.**

15 Section 1898(b)(1) of the Social Security Act (42
16 U.S.C. 1395iii(b)(1)), as amended by section 3(e)(3) of
17 the IMPACT Act of 2014 (Public Law 113-185), is
18 amended by striking “\$195,000,000” and inserting “\$0”.

19 **SEC. 21. RULE OF CONSTRUCTION.**

20 Except as explicitly provided in this Act, nothing in
21 this Act, including the amendments made by this Act,
22 shall be construed as preventing the use of notice and com-
23 ment rulemaking in the implementation of the provisions
24 of, and the amendments made by, this Act.

