

112TH CONGRESS  
1ST SESSION

# S. 454

To amend titles XVIII and XIX of the Social Security Act to prevent fraud, waste, and abuse under Medicare, Medicaid, and CHIP, and for other purposes.

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## IN THE SENATE OF THE UNITED STATES

MARCH 2, 2011

Mr. GRASSLEY introduced the following bill; which was read twice and referred to the Committee on Finance

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## A BILL

To amend titles XVIII and XIX of the Social Security Act to prevent fraud, waste, and abuse under Medicare, Medicaid, and CHIP, 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 “Strengthening Program Integrity and Accountability in  
6 Health Care Act of 2011”.

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

Sec. 1. Short title; table of contents.

Sec. 2. Enhanced Medicare and Medicaid program integrity provisions.

- Sec. 3. Requirements for the transmission of management implication reports by the HHS OIG.
- Sec. 4. Medical ID theft information sharing program and clearinghouse.
- Sec. 5. Permissive exclusion from Federal health care programs expanded to individuals and entities affiliated with sanctioned entities.
- Sec. 6. Public availability of Medicare claims data.
- Sec. 7. Medicaid exclusion from participation relating to certain ownership, control, and management affiliations.
- Sec. 8. Payment for illegal unapproved drugs.
- Sec. 9. Requiring individuals or entities that participate in or conduct activities under Federal health care programs to comply with certain Congressional requests.

1 **SEC. 2. ENHANCED MEDICARE AND MEDICAID PROGRAM**

2 **INTEGRITY PROVISIONS.**

3 (a) MANDATORY SUSPENSION OF MEDICARE AND  
 4 MEDICAID PAYMENTS PENDING INVESTIGATION OF  
 5 CREDIBLE ALLEGATIONS OF FRAUD.—Section 1862(o)(1)  
 6 of the Social Security Act (42 U.S.C. 1395y(o)(1)) is  
 7 amended by striking “may” and inserting “shall”.

8 (b) EXTENSION OF NUMBER OF DAYS IN WHICH  
 9 MEDICARE CLAIMS ARE REQUIRED TO BE PAID IN  
 10 ORDER TO PREVENT OR COMBAT FRAUD, WASTE, OR  
 11 ABUSE.—

12 (1) PART A CLAIMS.—Section 1816(c)(2) of the  
 13 Social Security Act (42 U.S.C. 1395h(c)(2)) is  
 14 amended—

15 (A) in subparagraph (B)(ii)(V), by striking  
 16 “with respect” and inserting “subject to sub-  
 17 paragraph (D), with respect”; and

18 (B) by adding at the end the following new  
 19 subparagraph:

1           “(D)(i) Upon a determination by the Sec-  
2           retary that there is a likelihood of fraud, waste,  
3           or abuse involving a particular category of pro-  
4           viders of services or suppliers, categories of pro-  
5           viders of services or suppliers in a certain geo-  
6           graphic area, or individual providers of services  
7           or suppliers, the Secretary shall extend the  
8           number of calendar days described in subpara-  
9           graph (B)(ii)(V) to—

10                   “(I) up to 365 calendar days with re-  
11                   spect to claims submitted by—

12                           “(aa) categories of providers of  
13                           services or suppliers; or

14                           “(bb) categories of providers of  
15                           services or suppliers in a certain geo-  
16                           graphic area; or

17                   “(II) such time that the Secretary de-  
18                   termines is necessary to ensure that the  
19                   claims with respect to individual providers  
20                   of services or suppliers are clean claims.

21           “(ii) During the extended period of time  
22           under subclauses (I) and (II) of clause (ii), the  
23           Secretary shall engage in heightened scrutiny of  
24           claims, such as prepayment review and other

1 methods the Secretary determines to be appro-  
2 priate.

3 “(iii) Not later than 90 days after the date  
4 of enactment of this subparagraph and not less  
5 than annually thereafter, the Inspector General  
6 of the Department of Health and Human Serv-  
7 ices shall submit to the Secretary a report con-  
8 taining recommendations with respect to the  
9 application of this subparagraph and section  
10 1842(c)(2)(D). Not later than 60 days after re-  
11 ceiving such a report, the Secretary shall sub-  
12 mit to the Inspector General a written response  
13 to the recommendations contained in the report.

14 “(iv) There shall be no administrative or  
15 judicial review under section 1869, section  
16 1878, or otherwise of the implementation of  
17 this subparagraph by the Secretary.”.

18 (2) PART B CLAIMS.—Section 1842(c)(2) of the  
19 Social Security Act (42 U.S.C. 1395u(c)(2)) is  
20 amended—

21 (A) in subparagraph (B)(ii)(V), by striking  
22 “with respect” and inserting “subject to sub-  
23 paragraph (D), with respect”; and

24 (B) by adding at the end the following new  
25 subparagraph:

1           “(D)(i) Upon a determination by the Sec-  
2           retary that there is a likelihood of fraud, waste,  
3           or abuse involving a particular category of pro-  
4           viders of services or suppliers, categories of pro-  
5           viders of services or suppliers in a certain geo-  
6           graphic area, or individual providers of services  
7           or suppliers, the Secretary shall extend the  
8           number of calendar days described in subpara-  
9           graph (B)(ii)(V) to—

10                   “(I) up to 365 calendar days with re-  
11                   spect to claims submitted by—

12                           “(aa) categories of providers of  
13                           services or suppliers; or

14                           “(bb) categories of providers of  
15                           services or suppliers in a certain geo-  
16                           graphic area; or

17                   “(II) such time that the Secretary de-  
18                   termines is necessary to ensure that the  
19                   claims with respect to individual providers  
20                   of services or suppliers are clean claims.

21           “(ii) During the extended period of time  
22           under subclauses (I) and (II) of clause (ii), the  
23           Secretary shall engage in heightened scrutiny of  
24           claims, such as prepayment review and other

1 methods the Secretary determines to be appro-  
2 priate.

3 “(iii) There shall be no administrative or  
4 judicial review under section 1869, section  
5 1878, or otherwise of the implementation of  
6 this subparagraph by the Secretary.”.

7 (3) EFFECTIVE DATE.—

8 (A) IN GENERAL.—The amendments made  
9 by this subsection shall take effect on the date  
10 that is 6 months after the date of the enact-  
11 ment of this Act.

12 (B) EXPEDITING IMPLEMENTATION.—The  
13 Secretary shall promulgate regulations to carry  
14 out the amendments made by this subsection  
15 which may be effective and final immediately on  
16 an interim basis as of the date of publication of  
17 the interim final regulation. If the Secretary  
18 provides for an interim final regulation, the  
19 Secretary shall provide for a period of public  
20 comment on such regulation after the date of  
21 publication. The Secretary may change or revise  
22 such regulation after completion of the period  
23 of public comment.

1 **SEC. 3. REQUIREMENTS FOR THE TRANSMISSION OF MAN-**  
2 **AGEMENT IMPLICATION REPORTS BY THE**  
3 **HHS OIG.**

4 Section 1128J of the Social Security Act (42 U.S.C.  
5 1320a–7k) is amended by adding at the end the following  
6 new subsection:

7 “(f) TRANSMISSION OF MANAGEMENT IMPLICATION  
8 REPORTS BY THE HHS OIG.—

9 “(1) CONGRESSIONAL NOTIFICATION.—Not  
10 later than 30 days after the transmission by the In-  
11 spector General of the Department of Health and  
12 Human Services to another agency of the Depart-  
13 ment of Health and Human Services of a manage-  
14 ment implication report, the Inspector General shall  
15 notify the relevant committees of Congress of such  
16 transmission.

17 “(2) SECRETARIAL RESPONSE.—The Secretary  
18 shall respond to a management implication report  
19 transmitted under paragraph (1) not later than 90  
20 days after such transmission.

21 “(3) RELEVANT COMMITTEES OF CONGRESS  
22 DEFINED.—In this subsection, the term ‘relevant  
23 committees of Congress’ means the Committees on  
24 Ways and Means and Energy and Commerce of the  
25 House of Representatives and the Committee on Fi-  
26 nance of the Senate.”.

1 **SEC. 4. MEDICAL ID THEFT INFORMATION SHARING PRO-**  
2 **GRAM AND CLEARINGHOUSE.**

3 (a) ESTABLISHMENT.—Not later than 24 months  
4 after the date of enactment of this Act, the Secretary of  
5 Health and Human Services (in this section referred to  
6 as the “Secretary”), acting through the Administrator of  
7 the Centers for Medicare & Medicaid Services and in co-  
8 ordination with the Chairman of the Federal Trade Com-  
9 mission, shall establish an information sharing program  
10 regarding beneficiary medical ID theft under the pro-  
11 grams under titles XVIII, XIX, and XXI of the Social Se-  
12 curity Act (in this section referred to as the “program”).

13 (b) CONTENTS OF PROGRAM.—The program shall in-  
14 clude—

15 (1) the establishment of methods to identify  
16 and detect relevant warning signs of medical ID  
17 theft;

18 (2) the establishment of appropriate responses  
19 to such warning signs that would mitigate and pre-  
20 vent beneficiary medical ID theft; and

21 (3) the development of a detailed plan to up-  
22 date the program as appropriate, taking into consid-  
23 eration such warning signs and appropriate re-  
24 sponses.

25 (c) ESTABLISHMENT OF CLEARINGHOUSE.—The  
26 Secretary, in coordination with the Chairman of the Fed-

1 eral Trade Commission, shall establish a clearinghouse at  
 2 the Centers for Medicare & Medicaid Services that collects  
 3 reports of ID theft against beneficiaries under the pro-  
 4 grams under titles XVIII, XIX, and XXI of the Social Se-  
 5 curity Act from the Federal Trade Commission and other  
 6 sources determined appropriate by the Secretary. Such  
 7 clearinghouse shall be used to fight medical ID theft  
 8 against beneficiaries and to prevent the improper payment  
 9 of claims under such programs.

10 **SEC. 5. PERMISSIVE EXCLUSION FROM FEDERAL HEALTH**  
 11 **CARE PROGRAMS EXPANDED TO INDIVID-**  
 12 **UALS AND ENTITIES AFFILIATED WITH SANC-**  
 13 **TIONED ENTITIES.**

14 Section 1128(b)(15) of the Social Security Act (42  
 15 U.S.C. 1320a-7(b)(15)) is amended to read as follows:

16 “(15) INDIVIDUALS OR ENTITIES AFFILIATED  
 17 WITH A SANCTIONED ENTITY.—(A) Any of the fol-  
 18 lowing:

19 “(i) Any individual who—

20 “(I) is a person with an ownership or  
 21 control interest (as defined in section  
 22 1124(a)(3)) in a sanctioned entity or an  
 23 affiliated entity of such sanctioned entity  
 24 (or was a person with such an interest at  
 25 the time of any of the conduct that formed

1 a basis for the conviction or exclusion de-  
2 scribed in subparagraph (B)); and

3 “(II) knows or should know (as de-  
4 fined in section 1128A(i)(7)) (or knew or  
5 should have known) of such conduct.

6 “(ii) Any individual who is an officer or  
7 managing employee (as defined in section  
8 1126(b)) of a sanctioned entity or affiliated en-  
9 tity of such sanctioned entity (or was such an  
10 officer or managing employee at the time of any  
11 of the conduct that formed a basis for the con-  
12 viction or exclusion described in subparagraph  
13 (B)).

14 “(iii) Any affiliated entity of a sanctioned  
15 entity.

16 “(B) For purposes of this paragraph, the term  
17 ‘sanctioned entity’ means an entity—

18 “(i) that has been convicted of any offense  
19 described in subsection (a) or in paragraph (1),  
20 (2), or (3) of this subsection; or

21 “(ii) that has been excluded from partici-  
22 pation under a program under title XVIII or  
23 under a State health care program.

1           “(C)(i) For purposes of this paragraph, the  
2 term ‘affiliated entity’ means, with respect to a  
3 sanctioned entity—

4           “(I) an entity affiliated with such sanc-  
5 tioned entity; and

6           “(II) an entity that was so affiliated at the  
7 time of any of the conduct that formed the  
8 basis for the conviction or exclusion described  
9 in subparagraph (B).

10          “(ii) For purposes of clause (i), an entity  
11 shall be treated as affiliated with another entity  
12 if—

13           “(I) one of the entities is a person  
14 with an ownership or control interest (as  
15 defined in section 1124(a)(3)) in the other  
16 entity (or had such an interest at the time  
17 of any of the conduct that formed a basis  
18 for the conviction or exclusion described in  
19 subparagraph (B));

20           “(II) there is a person with an owner-  
21 ship or control interest (as defined in sec-  
22 tion 1124(a)(3)) in both entities (or had  
23 such an interest at the time of any of the  
24 conduct that formed a basis for the convic-

1           tion or exclusion described in subpara-  
2           graph (B)); or

3           “(III) there is a person who is an offi-  
4           cer or managing employee (as defined in  
5           section 1126(b)) of both entities (or was  
6           such an officer or managing employee at  
7           the time of any of the conduct that formed  
8           a basis for the conviction or exclusion de-  
9           scribed in subparagraph (B)).”.

10 **SEC. 6. PUBLIC AVAILABILITY OF MEDICARE CLAIMS DATA.**

11           Section 1128J of the Social Security Act (42 U.S.C.  
12 1320a–7k), as amended by section 3, is amended by add-  
13 ing at the end the following new subsection:

14           “(g) PUBLIC AVAILABILITY OF MEDICARE CLAIMS  
15 DATA.—

16           “(1) IN GENERAL.—The Secretary shall, to the  
17           extent consistent with applicable information, pri-  
18           vacy, security, and disclosure laws, including the  
19           regulations promulgated under the Health Insurance  
20           Portability and Accountability Act of 1996 and sec-  
21           tion 552a of title 5, United States Code, make avail-  
22           able to the public claims and payment data of the  
23           Department of Health and Human Services related  
24           to title XVIII, including data on payments made to  
25           any provider of services or supplier under such title.

1           “(2) IMPLEMENTATION.—Not later than De-  
2           cember 31, 2012, the Secretary shall promulgate  
3           regulations to carry out this subsection.”.

4 **SEC. 7. MEDICAID EXCLUSION FROM PARTICIPATION RE-**  
5                           **LATING TO CERTAIN OWNERSHIP, CONTROL,**  
6                           **AND MANAGEMENT AFFILIATIONS.**

7           Section 1902(a) of the Social Security Act (42 U.S.C.  
8           1396a(a)) is amended—

9                   (1) by striking “and” at the end of paragraph  
10           (82);

11                   (2) by striking the period at the end of para-  
12           graph (83) and inserting “; and”; and

13                   (3) by inserting after paragraph (83) the fol-  
14           lowing new paragraph:

15                   “(84) provide that the State agency described  
16           in paragraph (9) exclude, with respect to a period,  
17           any individual or entity from participation in the  
18           program under the State plan if such individual or  
19           entity owns, controls, or manages an entity that (or  
20           if such entity is owned, controlled, or managed by an  
21           individual or entity that)—

22                   “(A) has unpaid overpayments (as defined  
23           by the Secretary) under this title during such  
24           period determined by the Secretary or the State  
25           agency to be delinquent;

1           “(B) is suspended or excluded from par-  
2           ticipation under or whose participation is termi-  
3           nated under this title during such period; or

4           “(C) is affiliated with an individual or enti-  
5           ty that has been suspended or excluded from  
6           participation under this title or whose participa-  
7           tion is terminated under this title during such  
8           period.”.

9   **SEC. 8. PAYMENT FOR ILLEGAL UNAPPROVED DRUGS.**

10       (a) FINDINGS.—Congress finds that each year, the  
11 Medicaid program under title XIX of the Social Security  
12 Act (42 U.S.C. 1396 et seq.) pays millions of dollars in  
13 reimbursement for covered outpatient drugs that are not  
14 approved by the Food and Drug Administration under a  
15 new drug application under section 505(b) of the Federal  
16 Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) or an  
17 abbreviated new drug application under section 505(j) of  
18 such Act, or that such drug is not subject to such section  
19 or section 512 due to the application of section 201(p)  
20 of such Act (21 U.S.C. 321(p)).

21       (b) LISTING OF DRUGS AND DEVICES.—Section 510  
22 of the Federal Food, Drug and Cosmetic Act (21 U.S.C.  
23 360) is amended—

24           (1) in subsection (j)(1)(B)—

1 (A) in clause (i), by inserting “in the case  
2 of a drug, the authority under this Act that  
3 does not require such drug to be subject to sec-  
4 tion 505 and section 512,” after “labeling for  
5 such drug or device,”; and

6 (B) in clause (ii), by inserting “, in the  
7 case of a drug, the authority under this Act  
8 that does not require such drug to be subject to  
9 section 505 and section 512,” after “the label  
10 and package insert for such drug or device”;  
11 and

12 (2) in subsection (f)—

13 (A) by striking “(f) The Secretary” and in-  
14 serting the following:

15 “(f) INSPECTION BY PUBLIC OF REGISTRATION.—

16 “(1) IN GENERAL.—The Secretary”; and

17 (B) by adding at the end the following new  
18 paragraph:

19 “(2) LIST OF DRUGS THAT ARE NOT APPROVED  
20 UNDER SECTION 505 OR 512.—Not later than Janu-  
21 ary 1, 2012, the Secretary shall make available to  
22 the public on the Internet Web site of the Food and  
23 Drug Administration a list that includes, for each  
24 drug described in subsection (j)(1)(B)—

25 “(A) the drug;

1 “(B) the person who listed such drug; and

2 “(C) the authority under this Act that  
3 does not require such drug to be subject to sec-  
4 tion 505 and section 512, as provided by such  
5 person in such list.”.

6 (c) PAYMENT FOR COVERED OUTPATIENT DRUGS.—  
7 Section 1927 of the Social Security Act (42 U.S.C. 1396r–  
8 8) is amended by inserting at the end the following new  
9 subsection:

10 “(l) CONDITION.—Beginning January 1, 2012, no  
11 State shall make any payment under this section for any  
12 covered outpatient drug unless such State first verifies  
13 with the Food and Drug Administration that such covered  
14 outpatient drug has been approved by the Food and Drug  
15 Administration under a new drug application under sec-  
16 tion 505(b) of the Federal Food, Drug, and Cosmetic Act  
17 (21 U.S.C. 355(b)) or an abbreviated new drug application  
18 under section 505(j) of such Act, or that such drug is not  
19 subject to such section or section 512 due to the applica-  
20 tion of section 201(p) of such Act (21 U.S.C. 321(p)). The  
21 Secretary shall have the authority to proscribe regulations  
22 to create an information sharing protocol to allow States  
23 to verify that a covered outpatient drug has been approved  
24 by the Food and Drug Administration.”.

1 **SEC. 9. REQUIRING INDIVIDUALS OR ENTITIES THAT PAR-**  
2 **TICIPATE IN OR CONDUCT ACTIVITIES**  
3 **UNDER FEDERAL HEALTH CARE PROGRAMS**  
4 **TO COMPLY WITH CERTAIN CONGRESSIONAL**  
5 **REQUESTS.**

6 (a) IN GENERAL.—Section 1128J of the Social Secu-  
7 rity Act (42 U.S.C. 1320a–7k), as amended by section 6,  
8 is amended by adding at the end the following new sub-  
9 section:

10 “(h) COMPLIANCE WITH CERTAIN REQUESTS BY IN-  
11 DIVIDUALS AND ENTITIES THAT PARTICIPATE IN OR  
12 CONDUCT ACTIVITIES UNDER FEDERAL HEALTH CARE  
13 PROGRAMS.—

14 “(1) IN GENERAL.—Any individual or entity  
15 that participates in or conducts activities under a  
16 Federal health care program (as defined in section  
17 1128B(f)) shall, as a condition of such participation  
18 or such conduct, comply (at a time and in a manner  
19 specified by the Chairman or ranking member) with  
20 any request submitted by the Chairman or the rank-  
21 ing member of a relevant committee of Congress to  
22 the individual or entity for the following:

23 “(A) Documents.

24 “(B) Information.

25 “(C) Interviews.

1           “(2) RELEVANT COMMITTEE OF CONGRESS DE-  
2           FINED.—In this subsection, the term ‘relevant com-  
3           mittee of Congress’ means the Committees on Ways  
4           and Means and Energy and Commerce of the House  
5           of Representatives and the Committee on Finance of  
6           the Senate.”.

7           (b) EFFECTIVE DATE.—The amendments made by  
8           this section shall take effect on the date that is 2 years  
9           after the date of enactment of this Act.

○