

112TH CONGRESS  
2D SESSION

# S. 3604

To amend title XVIII of the Social Security Act to provide for the implementation of prescriber education programs and to establish requirements relating to the administration of antipsychotics to residents of skilled nursing facilities and nursing facilities under the Medicare and Medicaid programs, and for other purposes.

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## IN THE SENATE OF THE UNITED STATES

SEPTEMBER 20, 2012

Mr. KOHL (for himself, Mr. GRASSLEY, and Mr. BLUMENTHAL) introduced the following bill; which was read twice and referred to the Committee on Finance

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## A BILL

To amend title XVIII of the Social Security Act to provide for the implementation of prescriber education programs and to establish requirements relating to the administration of antipsychotics to residents of skilled nursing facilities and nursing facilities under the Medicare and Medicaid programs, 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.**

4 This Act may be cited as the “Improving Dementia  
5 Care Treatment for Older Adults Act of 2012”.

1 **SEC. 2. FINDINGS.**

2 Congress makes the following findings:

3 (1) More than 5,000,000 Americans are af-  
4 flicted with Alzheimer’s and related dementias, and  
5 that number is projected to reach as much as  
6 16,000,000 during the boomer’s “age wave” in the  
7 first half of the 21st century.

8 (2) Nearly 40 percent of individuals with de-  
9 mentia living in nursing homes receive antipsychotic  
10 drugs. No antipsychotics have been approved by the  
11 Food and Drug Administration to treat dementia.

12 (3) The potential harms of antipsychotics in  
13 frail elders are significant. Studies show that for  
14 every 53 patients with dementia who are treated  
15 with such a pharmaceutical, one will die. For every  
16 9 to 25 patients that benefit from an antipsychotic,  
17 one will die.

18 (4) A May 2011 report issued by the Office of  
19 Inspector General of the Department of Health and  
20 Human Services found that 305,000, or 14 percent,  
21 of the Nation’s 2,100,000 nursing home residents  
22 had at least one claim for antipsychotics. The report  
23 documented that 83 percent of Medicare claims for  
24 atypical antipsychotic drugs for elderly nursing home  
25 residents were associated with off-label conditions,

1 and that antipsychotics are often prescribed to man-  
2 age behavioral symptoms of patients with dementia.

3 (5) In 2005 and 2008, the Food and Drug Ad-  
4 ministration issued “black box warnings”—the  
5 strongest possible warning—stating that patients  
6 administered antipsychotics face a risk of death 1.6  
7 to 1.7 times greater than those who take a placebo.

8 (6) Despite these significant warnings,  
9 antipsychotic prescription rates in long-term care fa-  
10 cilities for patients with dementia and no diagnosis  
11 of psychosis are high. In 1999, 39 percent of elderly  
12 nursing home residents with dementia and aggres-  
13 sive behavioral symptoms received antipsychotics  
14 within a one-week period. By 2006, the use of  
15 antipsychotics among nursing home residents with  
16 dementia had increased by almost  $\frac{1}{3}$  to over  $\frac{1}{2}$  of  
17 these residents in some facilities. According to the  
18 Department of Health and Human Services, the cur-  
19 rent national average utilization rate of  
20 antipsychotics is 24 percent among long-stay resi-  
21 dents.

22 (7) The cost to taxpayers associated with the  
23 overutilization of antipsychotics is high. Since 2007,  
24 the Federal government has collected more than  
25 \$3,000,000,000 in settlements for illegal off-label

1 marketing of antipsychotics. In a June 2011 lawsuit,  
2 a Circuit Court Judge fined a company  
3 \$327,000,000 for deceptive marketing of an  
4 antipsychotic, and concluded that the company dis-  
5 played “a callous disregard to a patient’s right to  
6 have all information available”.

7 (8) In late 2011, the Chief Medical Officer of  
8 the Centers for Medicare & Medicaid Services testi-  
9 fied before the Special Committee on Aging of the  
10 Senate that 75 percent of Americans who are diag-  
11 nosed with Alzheimer’s will be admitted to a nursing  
12 home by age 80.

13 (9) Leading medical experts and organizations  
14 advise that individuals with dementia who display  
15 agitation and disruptive behaviors are often trying to  
16 communicate, and their failure to be able to do so  
17 can result in frustration and “acting out”. The re-  
18 sulting agitation and disruptive behaviors may sig-  
19 nify unmet needs or symptoms, including pain, con-  
20 stipation, negative responses to noise, or interaction  
21 with other individuals.

22 (10) The American Medical Directors Associa-  
23 tion advises practitioners to address the underlying  
24 causes and factors contributing to behavioral symp-  
25 toms through a “detailed review of a patient’s symp-

1 tom history and a careful assessment of the cir-  
2 cumstances in which problematic behavior occurs as  
3 a basis for both medication treatment and non-phar-  
4 macological interventions.”

5 (11) LeadingAge advises that “family members  
6 and professional caretakers ought to try first to un-  
7 derstand what the patient is trying to convey. Then,  
8 they can take appropriate action.” LeadingAge also  
9 notes that there is a “growing body of evidence that  
10 supports the effectiveness of behavioral modifications  
11 and non-pharmacological interventions to manage  
12 dementia.”

13 (12) In May 2012, the Centers for Medicare &  
14 Medicaid Services set a goal of reducing the utiliza-  
15 tion of antipsychotics in long-term care facilities by  
16 15 percent by the end of the year. The Partnership  
17 to Improve Dementia Care is a collaborative effort  
18 with industry and advocacy partners to improve  
19 training in nursing homes and to further develop ap-  
20 propriate alternatives to antipsychotics for nursing  
21 homes to use in providing care to residents who do  
22 not have a specific clinical indication for the use of  
23 those agents.

1 **SEC. 3. PRESCRIBER EDUCATION PROGRAMS.**

2 (a) IN GENERAL.—Section 1817(k) of the Social Se-  
 3 curity Act (42 U.S.C. 1395i(k)) is amended by adding at  
 4 the end the new paragraph:

5 “(9) PRESCRIBER EDUCATION PROGRAMS.—

6 “(A) FUNDING.—

7 “(i) TRANSFER.—The Managing  
 8 Trustee shall transfer to the Trust Fund,  
 9 under rules similar to the rules described  
 10 in paragraph (2)(C), an amount equal to  
 11 the penalties and damages obtained and  
 12 otherwise creditable to miscellaneous re-  
 13 ceipts of the general fund of the Treasury  
 14 obtained under sections 3729 through  
 15 3733 of title 31, United States Code  
 16 (known as the False Claims Act), in cases  
 17 involving claims related to the off-label  
 18 marketing of any prescription drug (other  
 19 than funds awarded to a relator, for res-  
 20 titution, or otherwise authorized by law).

21 “(ii) APPROPRIATED AMOUNTS TO AC-  
 22 COUNT FOR PRESCRIBER EDUCATION PRO-  
 23 GRAMS.—There are hereby appropriated to  
 24 the Account from the Trust Fund some  
 25 portion of such amounts transferred to the  
 26 Trust Fund under clause (i), to be avail-

1           able without further appropriation until ex-  
2           pended, for purposes of carrying out pre-  
3           scriber education programs and other ac-  
4           tivities in accordance with this paragraph.

5           “(B)    PRESCRIBER    EDUCATION    PRO-  
6           GRAMS.—

7                   “(i)    IN    GENERAL.—The    Secretary,  
8                   acting through the Centers for Medicare  
9                   and Medicaid Services, in consultation with  
10                  the Director of the Agency for Healthcare  
11                  Research and Quality and the Commis-  
12                  sioner of Food and Drugs, shall establish  
13                  and implement prescriber education pro-  
14                  grams.

15                  “(ii)   IMPLEMENTATION.—The    Sec-  
16                  retary shall establish and begin implemen-  
17                  tation of prescriber education programs  
18                  under this paragraph by not later than 6  
19                  months after the date on which funds are  
20                  first made available to the Account under  
21                  subparagraph (A).

22           “(C)    DEFINITIONS.—In this paragraph:

23                   “(i)    PRESCRIBER    EDUCATION    PRO-  
24                   GRAMS.—The term ‘prescriber education  
25                   program’ means a program to promote

1 high quality evidence-based treatment, in-  
2 cluding appropriate use of medications and  
3 non-pharmacologic interventions, through  
4 the development and dissemination of ob-  
5 jective, educational, and informational ma-  
6 terials to physicians and other prescribing  
7 practitioners, including such a program de-  
8 veloped by the Agency for Healthcare Re-  
9 search and Quality.

10 “(ii) OFF-LABEL MARKETING.—The  
11 term ‘off-label marketing’ means the mar-  
12 keting of a prescription drug for an indica-  
13 tion or use in a manner for which the drug  
14 has not been approved by the Food and  
15 Drug Administration.”.

16 (b) CONFORMING AMENDMENT.—Section  
17 1817(k)(2)(C)(iv) of the Social Security Act (42 U.S.C.  
18 1395i(k)(2)(C)(iv)) is amended by inserting “, for the con-  
19 duct of prescriber education programs and other activities  
20 in accordance with paragraph (9),” after “restitution”.

21 **SEC. 4. REVIEW AND REPORTING OF ANTIPSYCHOTICS**  
22 **PRESCRIBED TO RESIDENTS WITH DEMEN-**  
23 **TIA.**

24 (a) SKILLED NURSING FACILITIES.—



1           (1) IN GENERAL.—Section 1819(b) of the So-  
2           cial Security Act (42 U.S.C. 1395i–3(b)) is amended  
3           by adding at the end the following new paragraph:

4           “(9)     REVIEW     AND     REPORTING     OF  
5           ANTIPSYCHOTICS PRESCRIBED TO RESIDENTS WITH  
6           DEMENTIA.—

7           “(A) IN GENERAL.—As part of the drug  
8           regimen review process under this section (as  
9           described in section 483.60(c) of title 42, Code  
10          of Federal Regulations), the pharmacist con-  
11          ducting such review with respect to a skilled  
12          nursing facility shall—

13                 “(i) note any instance where an  
14                 antipsychotic was prescribed for a resident  
15                 of the facility with dementia for a use not  
16                 approved by the Food and Drug Adminis-  
17                 tration; and

18                 “(ii) submit to the administrator,  
19                 medical director, and director of nursing of  
20                 the facility a monthly report containing ag-  
21                 gregate information regarding any in-  
22                 stances noted under clause (i) during the  
23                 preceding month.

24           “(B) AVAILABILITY OF REPORTS.—A  
25           skilled nursing facility must—

1           “(i) upon receipt of a report sub-  
 2           mitted to the facility under subparagraph  
 3           (A)(ii), submit such report to the Sec-  
 4           retary; and

5           “(ii) make such reports available to  
 6           surveyors and the State Long-Term Care  
 7           Ombudsman described in section 712 of  
 8           the Older Americans Act of 1965.”.

9           (b) NURSING FACILITIES.—Section 1919(b) of the  
 10          Social Security Act (42 U.S.C. 1396r(b)) is amended by  
 11          adding at the end the following new paragraph:

12           “(9)     REVIEW     AND     REPORTING     OF  
 13           ANTIPSYCHOTICS PRESCRIBED TO RESIDENTS WITH  
 14           DEMENTIA.—

15           “(A) IN GENERAL.—As part of the drug  
 16           regimen review process under this section (as  
 17           described in section 483.60(c) of title 42, Code  
 18           of Federal Regulations), the pharmacist con-  
 19           ducting such review with respect to a nursing  
 20           facility shall—

21           “(i) note any instance where an  
 22           antipsychotic was prescribed for a resident  
 23           of the facility with dementia for a use not  
 24           approved by the Food and Drug Adminis-  
 25           tration; and

1           “(ii) submit to the administrator,  
2           medical director, and director of nursing of  
3           the facility a monthly report containing ag-  
4           gregate information regarding any in-  
5           stances noted under clause (i) during the  
6           preceding month.

7           “(B) AVAILABILITY OF REPORTS.—A nurs-  
8           ing facility must—

9           “(i) upon receipt of a report sub-  
10          mitted to the facility under subparagraph  
11          (A)(ii), submit such report to the Sec-  
12          retary; and

13          “(ii) make such reports available to  
14          surveyors and the State Long-Term Care  
15          Ombudsman described in section 712 of  
16          the Older Americans Act of 1965.”.

17          (c) EFFECTIVE DATE.—The amendments made by  
18          this section shall take effect on the date that is 1 year  
19          after the date of the enactment of this Act and apply to  
20          reviews conducted with respect to drugs dispensed or ad-  
21          ministered on or after such date.

1 **SEC. 5. STANDARDIZED PROTOCOL FOR OBTAINING IN-**  
 2 **FORMED CONSENT FROM AN OLDER ADULT**  
 3 **WITH DEMENTIA PRIOR TO PRESCRIBING AN**  
 4 **ANTIPSYCHOTIC.**

5 (a) STANDARDIZED PROTOCOL.—

6 (1) SKILLED NURSING FACILITIES.—Section  
 7 1819(b) of the Social Security Act (42 U.S.C.  
 8 1395i–3(b)), as amended by section 4, is amended  
 9 by adding at the end the following new paragraph:

10 “(10) STANDARDIZED PROTOCOL FOR OBTAIN-  
 11 ING INFORMED CONSENT FROM AN OLDER ADULT  
 12 WITH DEMENTIA PRIOR TO PRESCRIBING AN  
 13 ANTIPSYCHOTIC FOR A USE NOT APPROVED BY THE  
 14 FOOD AND DRUG ADMINISTRATION.—

15 “(A) PROTOCOL.—Not later than 180 days  
 16 after the date on which the Comptroller General  
 17 submits the report on State informed consent  
 18 laws under section 5(a)(3) of the Improving De-  
 19 mentia Care Treatment for Older Adults Act of  
 20 2012, the Secretary shall develop a standard-  
 21 ized protocol for skilled nursing facilities to ob-  
 22 tain informed consent from an older adult with  
 23 dementia (or, if applicable, the older adult’s  
 24 designated health care agent or other surrogate  
 25 under State law or regulation) prior to pre-  
 26 scribing an antipsychotic to the older adult for

1 a use not approved by the Food and Drug Ad-  
2 ministration.

3 “(B) REQUIREMENTS.—The standardized  
4 protocol developed under subparagraph (A)  
5 shall include the following:

6 “(i) A requirement, with respect to an  
7 older adult with dementia, that—

8 “(I) the facility, with the involve-  
9 ment of the prescriber, inform the  
10 older adult (or, if applicable, the older  
11 adult’s designated health care agent  
12 or other surrogate under State law or  
13 regulation) of—

14 “(aa) possible side effects  
15 and risks associated with the  
16 antipsychotic, including the men-  
17 tion of any ‘black box warning’;

18 “(bb) treatment modalities  
19 that were attempted prior to the  
20 use of the antipsychotic; and

21 “(cc) any other information  
22 the Secretary determines appro-  
23 priate;

24 “(II) the older adult (or, if appli-  
25 cable, the older adult’s designated

1 health care agent or other surrogate  
2 under State law or regulation) provide  
3 consent to the administration of the  
4 antipsychotic; and

5 “(III) the administration of the  
6 antipsychotic is in accordance with  
7 any plan of care that the older adult  
8 has in place, including non-pharma-  
9 cological interventions as appropriate  
10 that can effectively address underlying  
11 medical and environmental causes of  
12 behavioral disorders.

13 “(ii) An alternative protocol for ob-  
14 taining such informed consent—

15 “(I) in the case of emergencies;  
16 and

17 “(II) in the absence of a clearly  
18 identified designated health care agent  
19 or other surrogate under State law or  
20 regulation.

21 “(iii) Other items determined appro-  
22 priate by the Secretary.

23 “(C) TIMING OF INFORMED CONSENT.—

24 Under the standardized protocol, a skilled nurs-  
25 ing facility shall obtain informed consent—

1           “(i) prior to the initial prescribing of  
2           antipsychotics; or

3           “(ii) in the case of an individual al-  
4           ready prescribed antipsychotics when ad-  
5           mitted to a facility, the facility shall obtain  
6           informed consent if the facility maintains  
7           antipsychotic treatment after the first drug  
8           regimen review conducted with respect to  
9           the individual.

10          “(D) COMPLIANCE.—Effective beginning  
11          on the date that is 18 months after the date of  
12          enactment of the Improving Dementia Care  
13          Treatment for Older Adults Act of 2012, a  
14          skilled nursing facility shall comply with the  
15          standardized protocol developed under subpara-  
16          graph (A).

17          “(E) NO PREEMPTION.—Nothing in this  
18          paragraph shall preempt any provision of State  
19          or Federal law that provides broader rights  
20          with respect to informed consent for residents  
21          of facilities.”.

22          (2) NURSING FACILITIES.—Section 1919(b) of  
23          the Social Security Act (42 U.S.C. 1396r(b)), as  
24          amended by section 4, is amended by adding at the  
25          end the following new paragraph:

1           “(10) STANDARDIZED PROTOCOL FOR OBTAIN-  
2           ING INFORMED CONSENT FROM AN OLDER ADULT  
3           WITH DEMENTIA PRIOR TO PRESCRIBING AN  
4           ANTIPSYCHOTIC FOR A USE NOT APPROVED BY THE  
5           FOOD AND DRUG ADMINISTRATION.—

6                   “(A) PROTOCOL.—Not later than 180 days  
7                   after the date on which the Comptroller General  
8                   submits the report on State informed consent  
9                   laws under section 5(a)(3) of the Improving De-  
10                  mentia Care Treatment for Older Adults Act of  
11                  2012, the Secretary shall develop a standard-  
12                  ized protocol for nursing facilities to obtain in-  
13                  formed consent from an older adult with de-  
14                  mentia (or, if applicable, the older adult’s des-  
15                  ignated health care agent or other surrogate  
16                  under State law or regulation) prior to pre-  
17                  scribing an antipsychotic to the older adult for  
18                  a use not approved by the Food and Drug Ad-  
19                  ministration.

20                   “(B) REQUIREMENTS.—The standardized  
21                   protocol developed under subparagraph (A)  
22                   shall include the following:

23                           “(i) A requirement, with respect to an  
24                           older adult with dementia, that—



1           “(I) the facility, with the involve-  
2           ment of the prescriber, inform the  
3           older adult (or, if applicable, the older  
4           adult’s designated health care agent  
5           or other surrogate under State law or  
6           regulation) of—

7                   “(aa) possible side effects  
8                   and risks associated with the  
9                   antipsychotic, including the men-  
10                  tion of any ‘black box warning’;

11                  “(bb) treatment modalities  
12                  that were attempted prior to the  
13                  use of the antipsychotic; and

14                  “(cc) any other information  
15                  the Secretary determines appro-  
16                  priate;

17           “(II) the older adult (or, if appli-  
18           cable, the older adult’s designated  
19           health care agent or other surrogate  
20           under State law or regulation) provide  
21           consent to the administration of the  
22           antipsychotic; and

23           “(III) the administration of the  
24           antipsychotic is in accordance with  
25           any plan of care that the older adult

1 has in place, including non-pharma-  
2 cological interventions as appropriate  
3 that can effectively address underlying  
4 medical and environmental causes of  
5 behavioral disorders.

6 “(ii) An alternative protocol for ob-  
7 taining such informed consent—

8 “(I) in the case of emergencies;  
9 and

10 “(II) in the absence of a clearly  
11 identified designated health care agent  
12 or other surrogate under State law or  
13 regulation.

14 “(iii) Other items determined appro-  
15 priate by the Secretary.

16 “(C) TIMING OF INFORMED CONSENT.—

17 Under the standardized protocol, a nursing fa-  
18 cility shall obtain informed consent—

19 “(i) prior to the initial prescribing of  
20 antipsychotics; or

21 “(ii) in the case of an individual al-  
22 ready prescribed antipsychotics when ad-  
23 mitted to a facility, the facility shall obtain  
24 informed consent if the facility maintains  
25 antipsychotic treatment after the first drug

1           regimen review conducted with respect to  
2           the individual.

3           “(D) COMPLIANCE.—Effective beginning  
4           on the date that is 18 months after the date of  
5           enactment of the Improving Dementia Care  
6           Treatment for Older Adults Act of 2012, a  
7           nursing facility shall comply with the standard-  
8           ized protocol developed under subparagraph  
9           (A).

10           “(E) NO PREEMPTION.—Nothing in this  
11           paragraph shall preempt any provision of State  
12           or Federal law that provides broader rights  
13           with respect to informed consent for residents  
14           of facilities.”.

15           (3) GAO STUDY AND REPORT ON INFORMED  
16           CONSENT LAWS WITH RESPECT TO PRESCRIBING OF  
17           AN ANTIPSYCHOTIC.—

18           (A) STUDY.—The Comptroller General of  
19           the United States (in this paragraph referred to  
20           as the “Comptroller General”) shall conduct a  
21           study of State laws and regulations concerning  
22           informed consent with respect to the adminis-  
23           tration of an antipsychotic (or other  
24           psychoactive medication) with regard to the ef-  
25           fectiveness of such laws and practices in chang-

1           ing the frequency of prescribing of  
2           antipsychotics (or other psychoactive medica-  
3           tions) to older adults with dementia. The study  
4           shall include an analysis as to whether in the  
5           case of States that have not enacted such in-  
6           formed consent laws, such States have devel-  
7           oped other mechanisms to guide appropriate  
8           prescribing of antipsychotics in older adults  
9           with dementia.

10           (B) REPORT.—Not later than 180 days  
11           after the date of enactment of this Act, the  
12           Comptroller General shall submit to the Sec-  
13           retary and to Congress a report containing the  
14           results of the study conducted under subpara-  
15           graph (A), together with such recommendations  
16           as the Comptroller General determines appro-  
17           priate.

18           (b) DEVELOPMENT OF MEASURE OF UTILIZATION OF  
19           ANTIPSYCHOTICS FOR INCLUSION ON NURSING HOME  
20           COMPARE WEBSITE.—

21           (1) MEDICARE.—Section 1819(i) of the Social  
22           Security Act (42 U.S.C. 1395i–3(i)) is amended by  
23           adding at the end the following new paragraph:

24           “(3) DEVELOPMENT OF MEASURE OF UTILIZA-  
25           TION OF ANTIPSYCHOTICS.—

1           “(A) IN GENERAL.—The Secretary shall  
2 include a measure of the utilization of  
3 antipsychotics for each facility for inclusion on  
4 such website (or a successor website) as part of  
5 the quality measures or health inspection meas-  
6 ures, or both such measures, under the Five-  
7 Star Quality Rating System.

8           “(B) CONSIDERATIONS.—In developing the  
9 measure under subparagraph (A), the Secretary  
10 shall take into account special patient popu-  
11 lations, special care units, appropriate diag-  
12 noses, and other factors, as determined appro-  
13 priate by the Secretary.”.

14           (2) MEDICAID.—Section 1919(i) of the Social  
15 Security Act (42 U.S.C. 1396r(i)) is amended by  
16 adding at the end the following new paragraph:

17           “(3) DEVELOPMENT OF MEASURE OF UTILIZA-  
18 TION OF ANTIPSYCHOTICS.—

19           “(A) IN GENERAL.—The Secretary shall  
20 include a measure of the utilization of  
21 antipsychotics for each facility for inclusion on  
22 such website (or a successor website) as part of  
23 the quality measures or health inspection meas-  
24 ures, or both such measures, under the Five-  
25 Star Quality Rating System.

1           “(B) CONSIDERATIONS.—In developing the  
2           measure under subparagraph (A), the Secretary  
3           shall take into account special patient popu-  
4           lations, special care units, appropriate diag-  
5           noses, and other factors, as determined appro-  
6           priate by the Secretary.”.

7 **SEC. 6. GAO STUDY AND REPORT ON STANDARDIZED PRO-**  
8           **TOCOL FOR OBTAINING INFORMED CONSENT.**

9           (a) STUDY.—The Comptroller General of the United  
10 States (in this section referred to as the “Comptroller  
11 General”) shall conduct a study to analyze the impact of  
12 the standardized protocol for obtaining informed consent  
13 under sections 1819(b)(10) and 1919(b)(10) of the Social  
14 Security Act, as added by paragraphs (1) and (2), respec-  
15 tively, of section 5(a). Such study shall include an analysis  
16 of—

17           (1) whether changes in the utilization of  
18 antipsychotics in selected facilities resulted in im-  
19 proved quality of life for residents;

20           (2) whether changes in the utilization of  
21 antipsychotics in selected facilities resulted in trans-  
22 fer of residents to other settings for psychiatric care;

23           (3) whether selected facilities adopted greater  
24 use of alternative treatment modalities, including

1 non-pharmacologic interventions and individualized,  
 2 person-centered techniques;

3 (4) whether the standardized protocol resulted  
 4 in diminished access to antipsychotics among indi-  
 5 viduals with a diagnosis of mental illness;

6 (5) whether the standardized protocol resulted  
 7 in physicians and other prescribers switching from  
 8 prescribing antipsychotics to prescribing other  
 9 sedating psychoactive medications; and

10 (6) the prevalence of antipsychotic prescribing  
 11 for older adults outside of the skilled nursing facility  
 12 or nursing facility setting, including in hospitals and  
 13 assisted living communities.

14 (b) REPORT.—Not later than 2 years after the com-  
 15 pliance date under subparagraph (D) of each of such sec-  
 16 tions 1819(b)(10) and 1919(b)(10), the Comptroller Gen-  
 17 eral shall submit to the Secretary and to Congress a report  
 18 containing the results of the study conducted under sub-  
 19 section (a), together with such recommendations as the  
 20 Comptroller General determines appropriate.

21 **SEC. 7. IOM STUDY AND REPORT ON USE OF**  
 22 **ANTIPSYCHOTICS ACROSS CARE SETTINGS.**

23 (a) STUDY.—

24 (1) IN GENERAL.—The Secretary of Health and  
 25 Human Services (in this section referred to as the

1 “Secretary”) shall seek to enter into an agreement  
2 with the Institute of Medicine of the National Acad-  
3 emies to conduct a study on—

4 (A) the appropriate prescribing of  
5 antipsychotics for hospital inpatients; and

6 (B) whether documentation of  
7 antipsychotic use in patients with dementia is  
8 provided during transitions of care from hos-  
9 pitals to other care settings.

10 (2) ANALYSIS OF PATTERNS OF USE.—The  
11 study conducted under paragraph (1) shall include  
12 an analysis by the Institute of Medicine of the pat-  
13 terns of use of antipsychotics in older adults with  
14 dementia that originate in ambulatory settings.

15 (3) CONSULTATION.—Under the agreement  
16 under paragraph (1), the Institute of Medicine shall  
17 consult with leaders in the hospital and medical care  
18 sector, the long-term care industry, the pharmacy  
19 community, representatives of nursing home resi-  
20 dents and family caregivers, leading experts in psy-  
21 chiatry and geriatrics, and other entities or individ-  
22 uals determined appropriate by the Secretary in con-  
23 ducting the study under the preceding sentence.

24 (b) REPORT.—The agreement entered into under  
25 subsection (a) shall provide for the Institute of Medicine



1 to submit to the Secretary and to Congress a report con-  
2 taining the results of the study conducted under such sub-  
3 section.

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