

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.

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

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 displayed “a callous disregard to a patient’s right to
5 have all information available”.

7 (8) In late 2011, the Chief Medical Officer of
8 the Centers for Medicare & Medicaid Services testified before the Special Committee on Aging of the
9 Senate that 75 percent of Americans who are diagnosed with Alzheimer’s will be admitted to a nursing
10 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 resulting agitation and disruptive behaviors may signify
18 unmet needs or symptoms, including pain, constipation, negative responses to noise, or interaction
19 with other individuals.

22 (10) The American Medical Directors Association advises practitioners to address the underlying
23 causes and factors contributing to behavioral symptoms 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 cepts 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-

able without further appropriation until expended, for purposes of carrying out prescriber education programs and other activities in accordance with this paragraph.

“(B) PRESCRIBER EDUCATION PROGRAMS.—

“(i) IN GENERAL.—The Secretary, acting through the Centers for Medicare and Medicaid Services, in consultation with the Director of the Agency for Healthcare Research and Quality and the Commissioner of Food and Drugs, shall establish and implement prescriber education programs.

“(ii) IMPLEMENTATION.—The Secretary shall establish and begin implementation of prescriber education programs under this paragraph by not later than 6 months after the date on which funds are first made available to the Account under subparagraph (A).

“(C) DEFINITIONS.—In this paragraph:

“(i) PRESCRIBER EDUCATION PROGRAMS.—The term ‘prescriber education program’ means a program to promote

high quality evidence-based treatment, including appropriate use of medications and non-pharmacologic interventions, through the development and dissemination of objective, educational, and informational materials to physicians and other prescribing practitioners, including such a program developed by the Agency for Healthcare Research and Quality.

“(ii) OFF-LABEL MARKETING.—The term ‘off-label marketing’ means the marketing of a prescription drug for an indication or use in a manner for which the drug has not been approved by the Food and Drug Administration.”.

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

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

(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-

ing the frequency of prescribing of antipsychotics (or other psychoactive medications) to older adults with dementia. The study shall include an analysis as to whether in the case of States that have not enacted such informed consent laws, such States have developed other mechanisms to guide appropriate prescribing of antipsychotics in older adults with dementia.

(B) REPORT.—Not later than 180 days after the date of enactment of this Act, the Comptroller General shall submit to the Secretary and to Congress a report containing the results of the study conducted under subparagraph (A), together with such recommendations as the Comptroller General determines appropriate.

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

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

“(3) DEVELOPMENT OF MEASURE OF UTILIZATION 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.

