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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

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Improving Dementia Care Treatment for Older Adults Act of 2012".

SEC. 2. FINDINGS.

Congress makes the following findings:

(1) More than 5,000,000 Americans are afflicted with Alzheimer's and related dementias, and that number is projected to reach as much as 16,000,000 during the boomer's ''age wave'' in the first half of the 21st century.

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

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

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

and that antipsychotics are often prescribed to manage behavioral symptoms of patients with dementia.

(5) In 2005 and 2008, the Food and Drug Administration issued ''black box warnings''—the strongest possible warning—stating that patients administered antipsychotics face a risk of death 1.6 to 1.7 times greater than those who take a placebo.

(6) Despite these significant warnings, antipsychotic prescription rates in long-term care facilities for patients with dementia and no diagnosis of psychosis are high. In 1999, 39 percent of elderly nursing home residents with dementia and aggressive behavioral symptoms received antipsychotics within a one-week period. By 2006, the use of antipsychotics among nursing home residents with dementia had increased by almost ⅓ to over ½ of these residents in some facilities. According to the Department of Health and Human Services, the current national average utilization rate of antipsychotics is 24 percent among long-stay residents.

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

marketing of antipsychotics. In a June 2011 lawsuit, a Circuit Court Judge fined a company $327,000,000 for deceptive marketing of an antipsychotic, and concluded that the company displayed ''a callous disregard to a patient's right to have all information available''.

(8) In late 2011, the Chief Medical Officer of the Centers for Medicare & Medicaid Services testified before the Special Committee on Aging of the Senate that 75 percent of Americans who are diagnosed with Alzheimer's will be admitted to a nursing home by age 80.

(9) Leading medical experts and organizations advise that individuals with dementia who display agitation and disruptive behaviors are often trying to communicate, and their failure to be able to do so can result in frustration and ''acting out''. The resulting agitation and disruptive behaviors may signify unmet needs or symptoms, including pain, constipation, negative responses to noise, or interaction with other individuals.

(10) The American Medical Directors Association advises practitioners to address the underlying causes and factors contributing to behavioral symptoms through a ''detailed review of a patient's symp-

tom history and a careful assessment of the circumstances in which problematic behavior occurs as a basis for both medication treatment and non-pharmacological interventions.''

(11) LeadingAge advises that ''family members and professional caretakers ought to try first to understand what the patient is trying to convey. Then, they can take appropriate action.'' LeadingAge also notes that there is a ''growing body of evidence that supports the effectiveness of behavioral modifications and non-pharmacological interventions to manage dementia.''

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

SEC. 3. PRESCRIBER EDUCATION PROGRAMS.

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

"(9) PRESCRIBER EDUCATION PROGRAMS.—

"(A) FUNDING.—

"(i) TRANSFER.—The Managing Trustee shall transfer to the Trust Fund, under rules similar to the rules described in paragraph (2)(C), an amount equal to the penalties and damages obtained and otherwise creditable to miscellaneous receipts of the general fund of the Treasury obtained under sections 3729 through 3733 of title 31, United States Code (known as the False Claims Act), in cases involving claims related to the off-label marketing of any prescription drug (other than funds awarded to a relator, for restitution, or otherwise authorized by law).

"(ii) APPROPRIATED AMOUNTS TO ACCOUNT FOR PRESCRIBER EDUCATION PROGRAMS.—There are hereby appropriated to the Account from the Trust Fund some portion of such amounts transferred to the 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 DEMENTIA.

(a) SKILLED NURSING FACILITIES.—

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

"(9) REVIEW AND REPORTING OF ANTIPSYCHOTICS PRESCRIBED TO RESIDENTS WITH DEMENTIA.—

"(A) IN GENERAL.—As part of the drug regimen review process under this section (as described in section 483.60(c) of title 42, Code of Federal Regulations), the pharmacist conducting such review with respect to a skilled nursing facility shall—

"(i) note any instance where an antipsychotic was prescribed for a resident of the facility with dementia for a use not approved by the Food and Drug Administration; and

"(ii) submit to the administrator, medical director, and director of nursing of the facility a monthly report containing aggregate information regarding any instances noted under clause (i) during the preceding month.

"(B) AVAILABILITY OF REPORTS.—A skilled nursing facility must—

"(i) upon receipt of a report submitted to the facility under subparagraph (A)(ii), submit such report to the Secretary; and

"(ii) make such reports available to surveyors and the State Long-Term Care Ombudsman described in section 712 of the Older Americans Act of 1965.".

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

"(9) REVIEW AND REPORTING OF ANTIPSYCHOTICS PRESCRIBED TO RESIDENTS WITH DEMENTIA.—

"(A) IN GENERAL.—As part of the drug regimen review process under this section (as described in section 483.60(c) of title 42, Code of Federal Regulations), the pharmacist conducting such review with respect to a nursing facility shall—

"(i) note any instance where an antipsychotic was prescribed for a resident of the facility with dementia for a use not approved by the Food and Drug Administration; and

"(ii) submit to the administrator, medical director, and director of nursing of the facility a monthly report containing aggregate information regarding any instances noted under clause (i) during the preceding month.

"(B) AVAILABILITY OF REPORTS.—A nursing facility must—

"(i) upon receipt of a report submitted to the facility under subparagraph (A)(ii), submit such report to the Secretary; and

"(ii) make such reports available to surveyors and the State Long-Term Care Ombudsman described in section 712 of the Older Americans Act of 1965.".

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

SEC. 5. STANDARDIZED PROTOCOL FOR OBTAINING INFORMED CONSENT FROM AN OLDER ADULT WITH DEMENTIA PRIOR TO PRESCRIBING AN ANTIPSYCHOTIC.

(a) STANDARDIZED PROTOCOL.—

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

"(10) STANDARDIZED PROTOCOL FOR OBTAINING INFORMED CONSENT FROM AN OLDER ADULT WITH DEMENTIA PRIOR TO PRESCRIBING AN ANTIPSYCHOTIC FOR A USE NOT APPROVED BY THE FOOD AND DRUG ADMINISTRATION.—

"(A) PROTOCOL.—Not later than 180 days after the date on which the Comptroller General submits the report on State informed consent laws under section 5(a)(3) of the Improving Dementia Care Treatment for Older Adults Act of 2012, the Secretary shall develop a standardized protocol for skilled nursing facilities to obtain informed consent from an older adult with dementia (or, if applicable, the older adult's designated health care agent or other surrogate under State law or regulation) prior to prescribing an antipsychotic to the older adult for

a use not approved by the Food and Drug Administration.

"(B) REQUIREMENTS.—The standardized protocol developed under subparagraph (A) shall include the following:

"(i) A requirement, with respect to an older adult with dementia, that—

"(I) the facility, with the involvement of the prescriber, inform the older adult (or, if applicable, the older adult's designated health care agent or other surrogate under State law or regulation) of—

"(aa) possible side effects and risks associated with the antipsychotic, including the mention of any 'black box warning';

"(bb) treatment modalities that were attempted prior to the use of the antipsychotic; and

"(cc) any other information the Secretary determines appropriate;

"(II) the older adult (or, if applicable, 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—

"(i) prior to the initial prescribing of antipsychotics; or

"(ii) in the case of an individual already prescribed antipsychotics when admitted to a facility, the facility shall obtain informed consent if the facility maintains antipsychotic treatment after the first drug regimen review conducted with respect to the individual.

"(D) COMPLIANCE.—Effective beginning on the date that is 18 months after the date of enactment of the Improving Dementia Care Treatment for Older Adults Act of 2012, a skilled nursing facility shall comply with the standardized protocol developed under subparagraph (A).

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

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

"(10) STANDARDIZED PROTOCOL FOR OBTAINING INFORMED CONSENT FROM AN OLDER ADULT WITH DEMENTIA PRIOR TO PRESCRIBING AN ANTIPSYCHOTIC FOR A USE NOT APPROVED BY THE FOOD AND DRUG ADMINISTRATION.—

"(A) PROTOCOL.—Not later than 180 days after the date on which the Comptroller General submits the report on State informed consent laws under section 5(a)(3) of the Improving Dementia Care Treatment for Older Adults Act of 2012, the Secretary shall develop a standardized protocol for nursing facilities to obtain informed consent from an older adult with dementia (or, if applicable, the older adult's designated health care agent or other surrogate under State law or regulation) prior to prescribing an antipsychotic to the older adult for a use not approved by the Food and Drug Administration.

"(B) REQUIREMENTS.—The standardized protocol developed under subparagraph (A) shall include the following:

"(i) A requirement, with respect to an older adult with dementia, that—

"(I) the facility, with the involvement of the prescriber, inform the older adult (or, if applicable, the older adult's designated health care agent or other surrogate under State law or regulation) of—

"(aa) possible side effects and risks associated with the antipsychotic, including the mention of any 'black box warning';

"(bb) treatment modalities that were attempted prior to the use of the antipsychotic; and

"(cc) any other information the Secretary determines appropriate;

"(II) the older adult (or, if applicable, the older adult's designated health care agent or other surrogate under State law or regulation) provide consent to the administration of the antipsychotic; and

"(III) the administration of the antipsychotic is in accordance with any plan of care that the older adult

has in place, including non-pharmacological interventions as appropriate that can effectively address underlying medical and environmental causes of behavioral disorders.

"(ii) An alternative protocol for obtaining such informed consent—

"(I) in the case of emergencies; and

"(II) in the absence of a clearly identified designated health care agent or other surrogate under State law or regulation.

"(iii) Other items determined appropriate by the Secretary.

"(C) TIMING OF INFORMED CONSENT.—Under the standardized protocol, a nursing facility shall obtain informed consent—

"(i) prior to the initial prescribing of antipsychotics; or

"(ii) in the case of an individual already prescribed antipsychotics when admitted to a facility, the facility shall obtain informed consent if the facility maintains antipsychotic treatment after the first drug

regimen review conducted with respect to the individual.

"(D) COMPLIANCE.—Effective beginning on the date that is 18 months after the date of enactment of the Improving Dementia Care Treatment for Older Adults Act of 2012, a nursing facility shall comply with the standardized protocol developed under subparagraph (A).

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

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

(A) STUDY.—The Comptroller General of the United States (in this paragraph referred to as the "Comptroller General") shall conduct a study of State laws and regulations concerning informed consent with respect to the administration of an antipsychotic (or other psychoactive medication) with regard to the effectiveness 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.—

"(A) IN GENERAL.—The Secretary shall include a measure of the utilization of antipsychotics for each facility for inclusion on such website (or a successor website) as part of the quality measures or health inspection measures, or both such measures, under the Five-Star Quality Rating System.

"(B) CONSIDERATIONS.—In developing the measure under subparagraph (A), the Secretary shall take into account special patient populations, special care units, appropriate diagnoses, and other factors, as determined appropriate by the Secretary.".

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

"(3) DEVELOPMENT OF MEASURE OF UTILIZATION OF ANTIPSYCHOTICS.—

"(A) IN GENERAL.—The Secretary shall include a measure of the utilization of antipsychotics for each facility for inclusion on such website (or a successor website) as part of the quality measures or health inspection measures, or both such measures, under the Five-Star Quality Rating System.

"(B) CONSIDERATIONS.—In developing the measure under subparagraph (A), the Secretary shall take into account special patient populations, special care units, appropriate diagnoses, and other factors, as determined appropriate by the Secretary.".

SEC. 6. GAO STUDY AND REPORT ON STANDARDIZED PROTOCOL FOR OBTAINING INFORMED CONSENT.

(a) STUDY.—The Comptroller General of the United States (in this section referred to as the "Comptroller General") shall conduct a study to analyze the impact of the standardized protocol for obtaining informed consent under sections 1819(b)(10) and 1919(b)(10) of the Social Security Act, as added by paragraphs (1) and (2), respectively, of section 5(a). Such study shall include an analysis of—

(1) whether changes in the utilization of antipsychotics in selected facilities resulted in improved quality of life for residents;

(2) whether changes in the utilization of antipsychotics in selected facilities resulted in transfer of residents to other settings for psychiatric care;

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

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

(4) whether the standardized protocol resulted in diminished access to antipsychotics among individuals with a diagnosis of mental illness;

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

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

(b) REPORT.—Not later than 2 years after the compliance date under subparagraph (D) of each of such sections 1819(b)(10) and 1919(b)(10), the Comptroller General shall submit to the Secretary and to Congress a report containing the results of the study conducted under subsection (a), together with such recommendations as the Comptroller General determines appropriate.

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

(a) STUDY.—

(1) IN GENERAL.—The Secretary of Health and 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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