

109TH CONGRESS  
2D SESSION

# S. 3897

To amend titles XI and XVIII of the Social Security Act to provide for the sharing of certain data collected by the Centers for Medicare & Medicaid Services with certain agencies, research centers and organizations, and congressional support agencies.

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## IN THE SENATE OF THE UNITED STATES

SEPTEMBER 14, 2006

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

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## A BILL

To amend titles XI and XVIII of the Social Security Act to provide for the sharing of certain data collected by the Centers for Medicare & Medicaid Services with certain agencies, research centers and organizations, and congressional support agencies.

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 “Medicare Data Access  
5 and Research Act”.

6 **SEC. 2. FINDINGS.**

7       Congress makes the following findings:

(2) Data from the new Medicare drug benefit can be linked with hospital, ambulatory care, and other data to create a new comprehensive resource for the study of drug safety and effectiveness of medical care in older adults and low-income, disabled, and vulnerable populations. With appropriate protections for privacy, this data should be available to the Food and Drug Administration, the Centers for Disease Control and Prevention, the Agency for Healthcare Research and Quality, and the National Institutes of Health, and university-based research centers and other research organizations interested in furthering the public health through research on the safety, effectiveness, and quality of health care services provided under the Medicare program under title XVIII of the Social Security Act.

24 (3) Timely and ready access to certain data  
25 from the new Medicare drug benefit will allow con-

1 gressional support agencies to inform and advise  
2 Congress on the cost, scope, and impact of the new  
3 benefit and assess its quality.

4 **SEC. 3. DRUG AND HEALTH CARE DATA RELEASE.**

5 (a) IN GENERAL.—Title XI of the Social Security Act  
6 (42 U.S.C. 1301 et seq.) is amended by inserting after  
7 section 1121 the following new sections:

8 “DRUG AND HEALTH CARE CLAIMS DATA RELEASE

9 “SEC. 1121A. (a) IN GENERAL.—Notwithstanding  
10 any provision under part D of title XVIII that limits the  
11 use of prescription drug data collected under such part,  
12 for the purpose of improving the public’s health, the Sec-  
13 retary, acting through the Centers for Medicare & Med-  
14 icaid Services, shall—

15 “(1) enter into data release agreements on an  
16 annual basis with the agencies described in sub-  
17 section (b) to provide access to relevant data sub-  
18 mitted by prescription drug plans and MA–PD plans  
19 under part D of title XVIII, excluding negotiated  
20 price concessions under such part (such as dis-  
21 counts, direct or indirect subsidies, rebates, and di-  
22 rect or indirect remunerations), and linked to hos-  
23 pital, physician, and other relevant medical claims,  
24 utilization, and diagnostic data collected under titles  
25 XVIII and XIX, including data from the uniform re-

1 porting systems established under section 1121(a);  
2 and

3       “(2) permit agencies described in such sub-  
4 section to link data provided under this section with  
5 other relevant health data, including survey data,  
6 vital statistics, and disease registries, as needed by  
7 the agency in order to accomplish its research objec-  
8 tives.

9       “(b) AGENCIES DESCRIBED.—The agencies described  
10 in this subsection are as follows:

11       “(1) The Food and Drug Administration.

12       “(2) The Centers for Disease Control and Pre-  
13 vention.

14       “(3) The Agency for Healthcare Research and  
15 Quality.

16       “(4) The National Institutes of Health.

17       “(c) USE OF THE DATA PROVIDED.—Data provided  
18 under a data release agreement under subsection (a)(1)  
19 shall only be used for the following purposes:

20       “(1) FDA.—In the case of the Food and Drug  
21 Administration, to enhance post marketing surveil-  
22 lance by—

23           “(A) studying patterns of drug and vaccine  
24 utilization over time after a drug has been  
25 placed on the market;

1                   “(B) studying health risks associated with  
2                   such utilization, particularly with respect to im-  
3                   proving the speed of risk identification in order  
4                   to mitigate or resolve such risks;

5                   “(C) studying drug utilization in order to  
6                   promote consumer education that would allow  
7                   consumers and health care providers to make  
8                   informed product choices and informed drug  
9                   compliance choices; and

10                  “(D) performing such other functions, con-  
11                  sistent with the purposes of this section and the  
12                  Agency’s mission, as are determined appro-  
13                  priate by the Secretary.

14                  “(2) CDC.—In the case of the Centers for Dis-  
15                  ease Control and Prevention, to—

16                  “(A) improve surveillance of clinical out-  
17                  breaks and emerging threats;

18                  “(B) study immunization rates;

19                  “(C) study outcomes of specific diseases;

20                  “(D) develop and monitor the use of pre-  
21                  ventive screening protocols using claims data;

22                  “(E) study drug and medical utilization in  
23                  order to promote consumer education and treat-  
24                  ment for specific public health risks; and

1                 “(F) perform such other functions, con-  
2                 sistent with the purposes of this section and the  
3                 Agency’s mission, as are determined appro-  
4                 priate by the Secretary.

5                 “(3) AHRQ.—In the case of the Agency for  
6                 Healthcare Research and Quality, to—

7                 “(A) carry out the Agency’s research obli-  
8                 gations under section 1013 of the Medicare  
9                 Prescription Drug, Improvement, and Mod-  
10                 ernization Act of 2003;

11                 “(B) conduct research consistent with the  
12                 Agency’s mission to improve the quality, safety,  
13                 efficiency, and effectiveness of health care; and

14                 “(C) perform such other functions, con-  
15                 sistent with the purposes of this section and  
16                 such mission, as are determined appropriate by  
17                 the Secretary.

18                 “(4) NIH.—In the case of the National Insti-  
19                 tutes of Health, to—

20                 “(A) help prevent, detect, diagnose, and  
21                 treat disease and disabilities; and

22                 “(B) perform such other functions, con-  
23                 sistent with the purposes of this section and the  
24                 Agency’s mission, as are determined appro-  
25                 priate by the Secretary.

1       “(d) TIMEFRAME FOR DATA RELEASE.—A data re-  
2 lease agreement entered into under this section shall pro-  
3 vide for the release of information as needed by the Agen-  
4 cy for the uses described in subsection (c).

5       “(e) DATA RELEASE PROCEDURES.—

6           “(1) DETERMINING APPROPRIATE LEVEL AND  
7 ELEMENTS OF DATA FOR RELEASE.—

8           “(A) IN GENERAL.—The Secretary shall  
9 establish a process to determine the appropriate  
10 level and elements of data to be released to an  
11 Agency under this section in order to ensure  
12 that the Agency, and researchers within the  
13 Agency, are able to conduct meaningful anal-  
14 yses while maintaining the confidentiality of the  
15 data provided under the data release agree-  
16 ment.

17           “(B) RELATIONSHIP TO PROCEDURES FOR  
18 RELEASE TO PRIVATE RESEARCHERS.—The  
19 process established under subparagraph (A)  
20 may be analogous to the process used by the  
21 Centers for Medicare & Medicaid Services for  
22 the release of data to private researchers.

23           “(2) AGENCY FEEDBACK ON ANALYSES CON-  
24 DUCTED.—The Secretary shall establish a process  
25 for Agencies that are provided data under a data re-

1 lease agreement under this section to provide the re-  
2 sults of the analyses conducted using such data to  
3 the Centers for Medicare & Medicaid Services for  
4 use in the administration and assessment of pro-  
5 grams administered by the Centers for Medicare &  
6 Medicaid Services, including the program under part  
7 D of title XVIII.

8       “(3) REVIEW OF DATA PROCEDURES.—The  
9 Secretary shall establish a process to review and up-  
10 date the following:

11           “(A) The processes established under para-  
12 graphs (1)(A) and (2).

13           “(B) Procedures for transmission and re-  
14 tention of data released under this section.

15       “(f) NOTIFICATION OF INACCURACIES DISCOVERED  
16 IN DATA PROVIDED.—The Secretary shall establish proce-  
17 dures to ensure that an Agency that is provided data  
18 under this section notifies the Secretary of any inaccura-  
19 cies discovered in the data by the Agency within a reason-  
20 able time of such discovery.

21       “(g) REPORT.—The Secretary shall include (begin-  
22 ning with 2007), as part of the annual report submitted  
23 to Congress under section 1875(b), an evaluation of the  
24 data release agreements entered into under subsection  
25 (a)(1), including a description of the reports and analyses

1 conducted by agencies using data provided under such an  
2 agreement.

3       “(h) AUTHORIZATION OF APPROPRIATIONS.—There  
4 are authorized to be appropriated such sums as are nec-  
5 essary to carry out the purposes of this section.

## 6 “RESEARCH CENTER AND ORGANIZATION DRUG AND

## 7 HEALTH CARE DATA USE

8       “SEC. 1121B. (a) IN GENERAL.—Notwithstanding  
9 any provision under part D of title XVIII that limits the  
10 use of prescription drug data collected under such part,  
11 for the purpose of improving the public’s health, the Sec-  
12 retary shall—

“(1) enter into data use agreements with the research centers and organizations described in subsection (b) to provide access to relevant data submitted by prescription drug plans and MA–PD plans under part D of title XVIII, excluding negotiated price concessions under such part (such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations), and linked to hospital, physician, and other relevant medical claims, utilization, and diagnostic data collected under titles XVIII and XIX, including data from the uniform reporting systems established under section 1121(a);

25               “(2) permit research centers and organizations  
26               described in such subsection to link data provided

1 under this section with other relevant health data,  
2 including survey data, vital statistics, and disease  
3 registries, as needed by the research center or orga-  
4 nization in order to accomplish its research objec-  
5 tives; and

6       “(3) prepare the linked sets of data described  
7 in paragraph (1) for release not later than July 1,  
8 2007.

9       “(b) RESEARCH CENTERS AND ORGANIZATIONS DE-  
10 SCRIBED.—The research centers and organizations de-  
11 scribed in this subsection are as follows:

12       “(1) A University-based research center.

13       “(2) Any other research center or organiza-  
14 tion—

15           “(A) whose primary mission is to conduct  
16 public health research; and

17           “(B) which the Secretary determines can  
18 appropriately conduct analyses consistent with  
19 the purposes of this section.

20       “(c) USE OF DATA AND PENALTIES.—

21       “(1) USE OF DATA.—

22           “(A) IN GENERAL.—Data provided to a re-  
23 search center or organization under a data use  
24 agreement under this section shall be used sole-  
25 ly for purposes of research on the safety, effec-

1 tiveness, and quality of, disparities in, and re-  
2 lated aspects of health care use by individuals  
3 entitled to, or enrolled for, benefits under part  
4 A of title XVIII, or enrolled for benefits under  
5 part B of such title, conducted for the purpose  
6 of developing and providing generalizable  
7 knowledge to inform the public health through  
8 scientific publication and other forms of public  
9 dissemination.

10                   “(B) APPROVAL BY REVIEW BOARD FOR  
11 THE PROTECTION OF HUMAN SUBJECTS.—Such  
12 use shall be approved by a review board for the  
13 protection of human subjects.

14                   “(C) REVIEW PROCESS.—The Secretary  
15 shall establish a review process to ensure that—

16                   “(i) data use agreements under this  
17 section include a detailed description of  
18 how the data is to be used under the  
19 agreement; and

20                   “(ii) such use is consistent with the  
21 purposes described in subparagraph (A).

22                   “(2) PENALTIES.—

23                   “(A) IN GENERAL.—A research center or  
24 organization who knowingly or intentionally  
25 uses data provided under a data use agreement

1           under this section for any purpose other than  
2           the purposes described in paragraph (1)(A)  
3           shall be subject, in addition to any other pen-  
4           alties that may be prescribed by law, to—

5               “(i) a civil money penalty of not less  
6               than \$25,000 for each infraction; and

7               “(ii) disqualification from receipt of  
8               any data under this section for not less  
9               than 2 years.

10           “(B) PROCEDURE.—The provisions of sec-  
11           tion 1128A (other than subsections (a) and (b)  
12           and the second sentence of subsection (f)) shall  
13           apply to a civil money penalty under this para-  
14           graph in the same manner as such provisions  
15           apply to a penalty or proceeding under section  
16           1128A(a).

17           “(d) RELEASE OF DATA.—

18               “(1) IN GENERAL.—A data use agreement en-  
19               tered into under subsection (a)(1) shall provide for  
20               the release of information according to a schedule  
21               approved by the Secretary under the criteria devel-  
22               oped in accordance with paragraph (2).

23               “(2) CRITERIA FOR APPROVING RESEARCH AP-  
24               PLICATIONS.—

1                     “(A) DEVELOPMENT.—The Secretary, in  
2                     consultation with health services researchers  
3                     and academicians, shall develop criteria for the  
4                     approval of a data use agreement under this  
5                     section.

6                     “(B) CRITERIA.—The criteria developed  
7                     under subparagraph (A) shall include the fol-  
8                     lowing requirements:

9                         “(i) The research center or organiza-  
10                     tion has well-documented scientific exper-  
11                     tise, a record of scholarship on the topic of  
12                     the proposed study, and a likelihood of  
13                     successful publication, as demonstrated by  
14                     a prior record of relevant publication by  
15                     key staff and other evidence of appropriate  
16                     scientific qualifications of the proposed re-  
17                     search team.

18                         “(ii) The research center or organiza-  
19                     tion demonstrates a credible capability to  
20                     conduct and complete the proposed study,  
21                     including experience with scientific inves-  
22                     tigations using similar types of data.

23                         “(iii) The research center or organiza-  
24                     tion demonstrates the public health impor-  
25                     tance of the proposed study, and the po-

1                   tential of such study to provide public  
2                   knowledge needed to improve the safety,  
3                   use, and outcomes of treatments, the ad-  
4                   ministration of the program under title  
5                   XVIII, and the care provided to individuals  
6                   entitled to, or enrolled for, benefits under  
7                   part A of title XVIII, or enrolled for bene-  
8                   fits under part B of such title.

9                   “(iv) The research center or organiza-  
10                  tion develops a data management plan that  
11                  describes in detail the measures that will  
12                  be implemented to safeguard the data and  
13                  protect the privacy of individuals entitled  
14                  to, or enrolled for, benefits under part A of  
15                  title XVIII, or enrolled for benefits under  
16                  part B of such title, including any pro-  
17                  posed data linkages.

18                   “(v) The research center or organiza-  
19                  tion enters into an agreement under which  
20                  the research center or organization agrees  
21                  to—

22                   “(I) place detailed results of the  
23                  proposed study in the public domain  
24                  through publication in a reasonable  
25                  timeframe, not to exceed 1 year after

1 completion of such study, including a  
2 thorough description of the methodology used to conduct the study;

3  
4 “(II) make available to the public, without charge, any product or  
5 tool developed using the data provided  
6 under this section; and

7  
8 “(III) not sell such data to other  
9 entities or create commercial data  
10 products (such as data extracts or analytical files) using such data.

11  
12 “(vi) The research center or organization and the proposed research team provide assurances that such team is independent from the sources of funding or  
13 any other party and has the right to independently and freely publish the scientific  
14 findings of the study.

15  
16 “(vii) Such other requirements, consistent with the purposes of this section, as  
17 the Secretary determines appropriate.

18  
19 “(3) TIMELY REVIEW AND ACTION ON REQUESTS.—The Secretary shall provide for timely review of, and action on, requests for a data use  
20 agreement under this section, taking into consider-

1           ation the reasonable needs of the research center or  
2           organization.

3           “(4) PUBLIC DISCLOSURE.—The Secretary shall  
4           make available to the public the criteria used to  
5           grant or deny data use agreements under the cri-  
6           teria developed under paragraph (2)(A).

7           “(e) FEEDBACK BY RESEARCH CENTER OR ORGANI-  
8           ZATION.—

9           “(1) NOTIFICATION OF INACCURACIES DISCOV-  
10           ERED IN DATA PROVIDED.—The Secretary shall es-  
11           tablish procedures to ensure that a research center  
12           or organization that is provided data under this sec-  
13           tion notifies the Secretary of any inaccuracies dis-  
14           covered in the data by the center or organization  
15           within a reasonable time of such discovery.

16           “(2) FEEDBACK ON DATA COLLECTION.—The  
17           Secretary shall permit researchers to provide feed-  
18           back on the collection of data with respect to the  
19           programs administered by the Centers for Medicare  
20           & Medicaid Services and make recommendations  
21           with respect to the collection of additional data ele-  
22           ments with respect to such programs.

23           “(f) CONFIDENTIALITY.—

24           “(1) DETERMINING APPROPRIATE LEVEL OF  
25           DATA TO BE PROVIDED.—The Secretary shall estab-

1 lish a process to determine the appropriate level of  
2 data to be provided to a research center or organiza-  
3 tion under this section in order to ensure that the  
4 center or organization, and researchers within the  
5 center or organization, are able to conduct meaning-  
6 ful analyses while maintaining the confidentiality of  
7 the data provided under the data use agreement.

8 “(2) SAFEGUARDS TO PROTECT CONFIDEN-  
9 TIALITY OF DATA PROVIDED.—

10 “(A) IN GENERAL.—The Secretary shall  
11 establish safeguards to protect the confiden-  
12 tiality of data after it is provided to a research  
13 center or organization under this section. Such  
14 safeguards shall not provide for greater disclo-  
15 sure by the research center or organization  
16 than is permitted under any of the following:

17 “(i) The Federal regulations (con-  
18 cerning the privacy of individually identifi-  
19 able health information) promulgated  
20 under section 264(c) of the Health Insur-  
21 ance Portability and Accountability Act of  
22 1996.

23 “(ii) Sections 552 or 552a of title 5,  
24 United States Code, with regard to the pri-

1                         vacy of individually identifiable beneficiary  
2                         health information.

3                         “(B) CONFIDENTIALITY OF PHYSICIANS  
4                         AND MEDICAL PRACTICES.—The safeguards es-  
5                         tablished under subparagraph (A) shall ensure  
6                         that the data provided to a research center or  
7                         organization under this section that identifies  
8                         individual physicians or medical practices is not  
9                         released by the research center or organization,  
10                         or otherwise made public.

11                         “(g) REPORT.—The Secretary shall include (begin-  
12                         ning with 2007), as part of the annual report submitted  
13                         to Congress under section 1875(b), an evaluation of the  
14                         agreements entered into under subsection (a).

15                         “(h) REASONABLE FEE.—The Secretary may charge  
16                         a research center or organization a reasonable fee based  
17                         on the cost of preparing and providing data to such center  
18                         or organization under this section.”.

19                         (b) CRITERIA DEVELOPMENT AND PUBLICATION.—  
20                         The Secretary shall develop and publish the criteria re-  
21                         quired under section 1121B(d)(2)(A) of the Social Secu-  
22                         rity Act, as added by subsection (a), not later than 180  
23                         days after the date of enactment of this Act.

1 **SEC. 4. ACCESS TO DATA ON PRESCRIPTION DRUG PLANS**2 **AND MEDICARE ADVANTAGE PLANS.**3 (a) IN GENERAL.—Section 1875 of the Social Secu-  
4 rity Act (42 U.S.C. 1395ll) is amended—5 (1) in the heading, by inserting “TO CONGRESS;  
6 PROVIDING INFORMATION TO CONGRESSIONAL SUP-  
7 PORT AGENCIES” after “AND RECOMMENDATIONS”;  
8 and9 (2) by adding at the end the following new sub-  
10 section:11 “(c) PROVIDING INFORMATION TO CONGRESSIONAL  
12 SUPPORT AGENCIES.—13 “(1) IN GENERAL.—Notwithstanding any provi-  
14 sion under part D that limits the use of prescription  
15 drug data collected under such part, upon the re-  
16 quest of a congressional support agency, the Sec-  
17 retary shall provide such agency with information  
18 submitted to, or compiled by, the Secretary under  
19 part D (subject to the restriction on disclosure under  
20 paragraph (2)), including—21 “(A) only with respect to congressional  
22 support agencies that make official baseline  
23 spending projections, conduct oversight studies  
24 mandated by Congress, or make official rec-  
25 ommendations on the program under this title  
26 to Congress—

1                         “(i) aggregate negotiated prices for  
2                         drugs covered under prescription drug  
3                         plans and MA–PD plans; and

4                         “(ii) bid information (described in sec-  
5                         tion 1860D–11(b)(2)(C)) submitted by  
6                         such plans; and

7                         “(B) access to drug event data submitted  
8                         by such plans under section 1860D–  
9                         15(d)(2)(A), except, with respect to data that  
10                         reveals prices negotiated with drug manufactur-  
11                         ers, such data shall only be available to con-  
12                         gressional support agencies that make official  
13                         baseline spending projections, conduct oversight  
14                         studies mandated by Congress, or make official  
15                         recommendations on the program under this  
16                         title to Congress.

17                         “(2) RESTRICTION ON DATA DISCLOSURE.—

18                         “(A) IN GENERAL.—Data provided to a  
19                         congressional support agency under this sub-  
20                         section shall not be disclosed, reported, or re-  
21                         leased in identifiable form.

22                         “(B) IDENTIFIABLE FORM.—For purposes  
23                         of subparagraph (A), the term ‘identifiable  
24                         form’ means any representation of information  
25                         that permits identification of a specific prescrip-

5                   “(3) TIMING.—The Secretary shall release data  
6                   under this subsection in a timeframe that enables  
7                   congressional support agencies to complete congres-  
8                   sional requests.

9           “(4) USE OF THE DATA PROVIDED.—Data pro-  
10           vided to a congressional support agency under this  
11           subsection shall only be used by such agency for car-  
12           rying out the functions and activities of the agency  
13           mandated by Congress.

14       “(5) CONFIDENTIALITY.—The Secretary shall  
15       establish safeguards to protect the confidentiality of  
16       data released under this subsection. Such safeguards  
17       shall not provide for greater disclosure than is per-  
18       mitted under any of the following:

19                     “(A) The Federal regulations (concerning  
20                     the privacy of individually identifiable health in-  
21                     formation) promulgated under section 264(c) of  
22                     the Health Insurance Portability and Account-  
23                     ability Act of 1996.

1           of individually identifiable beneficiary health in-  
2           formation.

3           “(6) DEFINITIONS.—In this subsection:

4           “(A) CONGRESSIONAL SUPPORT AGEN-  
5           CY.—The term ‘Congressional support agency’  
6           means—

7           “(i) the Medicare Payment Advisory  
8           Commission;

9           “(ii) the Congressional Research Serv-  
10           ice;

11           “(iii) the Congressional Budget Office;  
12           and

13           “(iv) the Government Accountability  
14           Office.

15           “(B) MA-PD PLAN.—The term ‘MA-PD  
16           plan’ has the meaning given such term in sec-  
17           tion 1860D-1(a)(3)(C).

18           “(C) PRESCRIPTION DRUG PLAN.—The  
19           term ‘prescription drug plan’ has the meaning  
20           given such term in section 1860D-41(a)(14).”.

21           (b) CONFORMING AMENDMENT.—Section 1805(b)(2)  
22           of the Social Security Act (42 U.S.C. 1395b-6(b)(2)) is  
23           amended by adding at the end the following new subpara-  
24           graph:

1                     “(D) PART D.—Specifically, the Commis-  
2                     sion shall review payment policies with respect  
3                     to the Voluntary Prescription Drug Benefit  
4                     Program under part D, including—  
5                         “(i) the factors affecting expenditures;  
6                         “(ii) payment methodologies; and  
7                         “(iii) their relationship to access and  
8                         quality of care for Medicare beneficiaries.”.

○