

110TH CONGRESS  
1ST SESSION

**S.** \_\_\_\_\_

To amend title XVIII of the Social Security Act to provide for drug and health care claims data release.

---

IN THE SENATE OF THE UNITED STATES

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

---

**A BILL**

To amend title XVIII of the Social Security Act to provide for drug and health care claims data release.

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 “Access to Medicare  
5 Data Act of 2007”.

6 **SEC. 2. DRUG AND HEALTH CARE CLAIMS DATA RELEASE.**

7 (a) IN GENERAL.—Section 1860D–42 of the Social  
8 Security Act (42 U.S.C. 1395w–152) is amended by add-  
9 ing at the end the following new subsection:

1           “(c) DRUG AND HEALTH CARE CLAIMS DATA RE-  
2 LEASE.—

3           “(1) DRUG AND HEALTH CARE CLAIMS DATA  
4 RELEASE.—Notwithstanding any provision under  
5 this part that limits the use of prescription drug  
6 data collected under this part, for the purpose of im-  
7 proving the public’s health through research on the  
8 safety, effectiveness, and quality of health care serv-  
9 ices provided under the program under this title, the  
10 Secretary shall—

11                   “(A) utilize such data collected; and

12                   “(B) acting through the Centers for Medi-  
13 care & Medicaid Services—

14                           “(i) enter into data release agree-  
15 ments on an annual basis with the agen-  
16 cies described in paragraph (2) to provide  
17 access to relevant data submitted by pre-  
18 scription drug plans and MA–PD plans  
19 under this part, excluding negotiated price  
20 concessions (such as discounts, direct or  
21 indirect subsidies, rebates, and direct or  
22 indirect remunerations), and linked to hos-  
23 pital, physician, and other relevant medical  
24 claims, utilization, and diagnostic data col-  
25 lected under this title and title XIX; and

1           “(ii) permit agencies described in  
2           paragraph (2) to link data provided under  
3           this subsection with other relevant health  
4           data, including survey data, vital statistics,  
5           and disease registries, as needed by the  
6           agency in order to accomplish its research  
7           objectives.

8           “(2) AGENCIES DESCRIBED.—The agencies de-  
9           scribed in this paragraph are as follows:

10           “(A) The Food and Drug Administration.

11           “(B) The Centers for Disease Control and  
12           Prevention.

13           “(C) The Agency for Healthcare Research  
14           and Quality.

15           “(D) The National Institutes of Health.

16           “(E) Any other agency or center within the  
17           Department of Health and Human Services as  
18           the Secretary determines appropriate.

19           “(3) USE OF THE DATA PROVIDED.—Data pro-  
20           vided under a data release agreement under para-  
21           graph (1)(B)(i) shall only be used for the following  
22           purposes:

23           “(A) FDA.—In the case of the Food and  
24           Drug Administration, to enhance postmarketing  
25           surveillance by—

1 “(i) studying health risks associated  
2 with such utilization, particularly with re-  
3 spect to improving the speed of risk identi-  
4 fication in order to mitigate or resolve such  
5 risks; and

6 “(ii) performing such other functions,  
7 consistent with the purposes of this sub-  
8 section and the mission of the Food and  
9 Drug Administration, as are determined  
10 appropriate by the Secretary.

11 “(B) CDC.—In the case of the Centers for  
12 Disease Control and Prevention, to—

13 “(i) improve surveillance of clinical  
14 outbreaks and emerging threats;

15 “(ii) study immunization rates;

16 “(iii) study outcomes of specific dis-  
17 eases;

18 “(iv) develop and monitor the use of  
19 preventive screening protocols using claims  
20 data;

21 “(v) study drug and medical utiliza-  
22 tion in order to promote consumer edu-  
23 cation and treatment for specific public  
24 health risks; and

1           “(vi) perform such other functions,  
2           consistent with the purposes of this sub-  
3           section and the mission of the Centers for  
4           Disease Control and Prevention, as are de-  
5           termined appropriate by the Secretary.

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

8           “(i) carry out the research obligations  
9           of the Agency for Healthcare Research and  
10          Quality under section 1013 of the Medi-  
11          care Prescription Drug, Improvement, and  
12          Modernization Act of 2003;

13          “(ii) conduct research consistent with  
14          the mission of the Agency for Healthcare  
15          Research and Quality to improve the qual-  
16          ity, safety, efficiency, and effectiveness of  
17          health care; and

18          “(iii) perform such other functions,  
19          consistent with the purposes of this sub-  
20          section and such mission, as are deter-  
21          mined appropriate by the Secretary.

22          “(D) NIH.—In the case of the National  
23          Institutes of Health, to—

24          “(i) help prevent, detect, diagnose,  
25          and treat disease and disabilities; and

1           “(ii) perform such other functions,  
2           consistent with the purposes of this sub-  
3           section and the mission of the National In-  
4           stitutes of Health, as are determined ap-  
5           propriate by the Secretary.

6           “(E) OTHER AGENCY OR CENTER WITHIN  
7           THE DEPARTMENT OF HEALTH AND HUMAN  
8           SERVICES.—In the case of an agency or center  
9           described in paragraph (2)(E), to conduct re-  
10          search, consistent with the purposes of this sub-  
11          section and the activities conducted under sub-  
12          paragraphs (A) through (D), as determined ap-  
13          propriate by the Secretary.

14          “(4) TIMEFRAME FOR DATA RELEASE.—A data  
15          release agreement entered into under this subsection  
16          shall provide for the release of information as needed  
17          by an agency described in paragraph (2) for the uses  
18          described in paragraph (3).

19          “(5) DATA RELEASE PROCEDURES.—

20                 “(A) DETERMINING APPROPRIATE LEVEL  
21                 AND ELEMENTS OF DATA FOR RELEASE.—

22                         “(i) IN GENERAL.—The Secretary  
23                         shall establish a process to determine the  
24                         appropriate level and elements of data to  
25                         be released to an agency described in para-

1 graph (2) under this subsection in order to  
2 ensure that the agency, and researchers  
3 within the agency, are able to conduct  
4 meaningful analyses while maintaining the  
5 confidentiality of the data provided under  
6 the data release agreement.

7 “(ii) RELATIONSHIP TO PROCEDURES  
8 FOR RELEASE TO PRIVATE RESEARCH-  
9 ERS.—The process established under  
10 clause (i) may be analogous to the process  
11 used by the Centers for Medicare & Med-  
12 icaid Services for the release of data to pri-  
13 vate researchers.

14 “(B) AGENCY FEEDBACK ON ANALYSES  
15 CONDUCTED.—The Secretary shall establish a  
16 process for agencies described in paragraph (2)  
17 that are provided data under a data release  
18 agreement under this subsection to provide the  
19 results of the analyses conducted using such  
20 data to the Centers for Medicare & Medicaid  
21 Services for use in the administration and as-  
22 sessment of programs administered by the Cen-  
23 ters for Medicare & Medicaid Services, includ-  
24 ing the program under this part.

1                   “(C) REVIEW OF DATA PROCEDURES.—

2                   The Secretary shall establish a process to re-  
3                   view and update the following:

4                   “(i) The processes established under  
5                   subparagraphs (A)(i) and (B).

6                   “(ii) Procedures for transmission and  
7                   retention of data released under this sub-  
8                   section.

9                   “(6) NOTIFICATION OF INACCURACIES DISCOV-  
10                  ERED IN DATA PROVIDED.—The Secretary shall es-  
11                  tablish procedures to ensure that an agency de-  
12                  scribed in paragraph (2) that is provided data under  
13                  this subsection notifies the Secretary of any inac-  
14                  curacies discovered in the data by the agency within  
15                  a reasonable time of such discovery.

16                  “(7) ACCESS BY CONTRACTORS AND SUB-  
17                  CONTRACTORS.—In the case of a public or private  
18                  entity that enters into a contract or subcontract with  
19                  an agency described in paragraph (2) to conduct ac-  
20                  tivities for such agency under this subsection, any  
21                  access by such entity to data from the program  
22                  under this title under this subsection shall be pro-  
23                  vided in accordance with, and subject to the same  
24                  requirements under, subsection (d) (other than the  
25                  requirement under paragraph (4)(B)(ii)(V)(aa) of

1 subsection (d), unless the Secretary determines that  
2 the application of such requirement is appropriate).

3 “(8) REPORT.—The Secretary shall report to  
4 Congress on an annual basis (beginning with 2008)  
5 an evaluation of the data release agreements entered  
6 into under paragraph (1)(B)(i), including a list and  
7 a description of the reports and analyses conducted  
8 by agencies using data provided under such an  
9 agreement.

10 “(9) AUTHORIZATION OF APPROPRIATIONS.—  
11 There are authorized to be appropriated such sums  
12 as are necessary to carry out the purposes of this  
13 subsection.”.

14 (b) RESEARCH CENTER AND ORGANIZATION DRUG  
15 AND HEALTH CARE DATA USE.—

16 (1) IN GENERAL.—Section 1860D–42 of the  
17 Social Security Act (42 U.S.C. 1395w–152), as  
18 amended by subsection (a), is amended by adding at  
19 the end the following new subsection:

20 “(d) RESEARCH CENTER AND ORGANIZATION DRUG  
21 AND HEALTH CARE DATA USE.—

22 “(1) IN GENERAL.—Notwithstanding any provi-  
23 sion under this part that limits the use of prescrip-  
24 tion drug data collected under this part, for the pur-  
25 pose of improving the public’s health through re-

1 search on the safety, effectiveness, and quality of  
2 health care services provided under the program  
3 under this title, the Secretary shall—

4 “(A) enter into data use agreements with  
5 the research centers and organizations de-  
6 scribed in paragraph (2) to provide access to  
7 relevant data submitted by prescription drug  
8 plans and MA–PD plans under this part, ex-  
9 cluding negotiated price concessions (such as  
10 discounts, direct or indirect subsidies, rebates,  
11 and direct or indirect remunerations), and  
12 linked to hospital, physician, and other relevant  
13 medical claims, utilization, and diagnostic data  
14 collected under this title and title XIX;

15 “(B) permit research centers and organiza-  
16 tions described in paragraph (2) to link data  
17 provided under this subsection with other rel-  
18 evant health data, including survey data, vital  
19 statistics, and disease registries, as needed by  
20 the research center or organization in order to  
21 accomplish its research objectives; and

22 “(C) prepare the linked sets of data de-  
23 scribed in subparagraph (A) for release not  
24 later than July 1, 2008.

1           “(2) RESEARCH CENTERS AND ORGANIZATIONS  
2 DESCRIBED.—The research centers and organiza-  
3 tions described in this paragraph are as follows:

4           “(A) A university-based research center.

5           “(B) Any other research center or organi-  
6 zation—

7           “(i) whose primary mission is to con-  
8 duct public research on the safety, effec-  
9 tiveness, and quality of health care serv-  
10 ices; and

11           “(ii) which the Secretary determines  
12 can appropriately conduct analyses con-  
13 sistent with the purposes of this sub-  
14 section.

15           “(3) USE OF DATA AND PENALTIES.—

16           “(A) USE OF DATA.—

17           “(i) IN GENERAL.—Data provided to  
18 a research center or organization under a  
19 data use agreement under this subsection  
20 shall be used solely for purposes of re-  
21 search on the safety, effectiveness, and  
22 quality of, disparities in, and related as-  
23 pects of, health care use by individuals en-  
24 titled to, or enrolled for, benefits under  
25 part A, or enrolled for benefits under part

1 B, conducted for the purpose of developing  
2 and providing generalizable knowledge to  
3 inform the public health through scientific  
4 publication and other forms of public dis-  
5 semination.

6 “(ii) APPROVAL BY REVIEW BOARD  
7 FOR THE PROTECTION OF HUMAN SUB-  
8 JECTS.—Such use shall be approved by a  
9 review board for the protection of human  
10 subjects.

11 “(iii) REVIEW PROCESS.—The Sec-  
12 retary shall establish a review process to  
13 ensure that—

14 “(I) data use agreements under  
15 this subsection include a detailed de-  
16 scription of how the data is to be used  
17 under the agreement; and

18 “(II) such use is consistent with  
19 the purposes described in clause (i).

20 “(B) PENALTIES.—

21 “(i) IN GENERAL.—A research center  
22 or organization who knowingly or inten-  
23 tionally uses data provided under a data  
24 use agreement under this subsection for  
25 any purpose other than the purposes de-

1 scribed in subparagraph (A)(i) shall be  
2 subject, in addition to any other penalties  
3 that may be prescribed by law, to—

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

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

10 “(ii) PROCEDURE.—The provisions of  
11 section 1128A (other than subsections (a)  
12 and (b) and the second sentence of sub-  
13 section (f)) shall apply to a civil money  
14 penalty under this subparagraph in the  
15 same manner as such provisions apply to a  
16 penalty or proceeding under section  
17 1128A(a).

18 “(4) RELEASE OF DATA.—

19 “(A) IN GENERAL.—A data use agreement  
20 entered into under paragraph (1)(A) shall pro-  
21 vide for the release of information—

22 “(i) according to a schedule approved  
23 by the Secretary under the criteria devel-  
24 oped in accordance with subparagraph (B);  
25 and

1                   “(ii) for a timeframe appropriate to  
2                   accomplish the research objective (as deter-  
3                   mined by the Secretary).

4                   “(B) CRITERIA FOR APPROVING RESEARCH  
5                   APPLICATIONS.—

6                   “(i) DEVELOPMENT.—The Secretary,  
7                   in consultation with health services re-  
8                   searchers and academicians, shall develop  
9                   criteria for the approval of a data use  
10                  agreement under this subsection.

11                  “(ii) CRITERIA.—The criteria devel-  
12                  oped under clause (i) shall include the fol-  
13                  lowing requirements:

14                  “(I) The research center or orga-  
15                  nization has well-documented sci-  
16                  entific expertise, a record of scholar-  
17                  ship on the topic of the proposed  
18                  study, and a likelihood of successful  
19                  publication, as demonstrated by a  
20                  prior record of relevant publication by  
21                  key staff and other evidence of appro-  
22                  priate scientific qualifications of the  
23                  proposed research team.

24                  “(II) The research center or or-  
25                  ganization demonstrates a credible ca-

1 pability to conduct and complete the  
2 proposed study, including experience  
3 with scientific investigations using  
4 similar types of data.

5 “(III) The research center or or-  
6 ganization demonstrates the public  
7 health importance of the proposed  
8 study, and the potential of such study  
9 to provide public knowledge needed to  
10 improve the safety, use, and outcomes  
11 of treatments, the administration of  
12 the program under this title, and the  
13 care provided to individuals entitled  
14 to, or enrolled for, benefits under part  
15 A, or enrolled for benefits under part  
16 B.

17 “(IV) The research center or or-  
18 ganization develops a data manage-  
19 ment plan that describes in detail the  
20 measures that will be implemented to  
21 safeguard the data and protect the  
22 privacy of individuals entitled to, or  
23 enrolled for, benefits under part A, or  
24 enrolled for benefits under part B, in-  
25 cluding any proposed data linkages.

1                   “(V) The research center or or-  
2                   ganization enters into an agreement  
3                   under which the research center or or-  
4                   ganization agrees to—

5                   “(aa) place detailed results  
6                   of the proposed study in the pub-  
7                   lic domain through publication in  
8                   a reasonable timeframe, not to  
9                   exceed 1 year after completion of  
10                  such study, including a thorough  
11                  description of the methodology  
12                  used to conduct the study;

13                  “(bb) make available to the  
14                  public, without charge, any prod-  
15                  uct or tool developed using the  
16                  data provided under this sub-  
17                  section; and

18                  “(cc) not sell such data to  
19                  other entities or create commer-  
20                  cial data products (such as data  
21                  extracts or analytical files) using  
22                  such data.

23                  “(VI) The research center or or-  
24                  ganization and the proposed research  
25                  team provide assurances that such

1 team is independent from the sources  
2 of funding or any other party and has  
3 the right to independently and freely  
4 publish the scientific findings of the  
5 study.

6 “(VII) Such other requirements,  
7 consistent with the purposes of this  
8 subsection, as the Secretary deter-  
9 mines appropriate.

10 “(C) TIMELY REVIEW AND ACTION ON RE-  
11 QUESTS.—The Secretary shall provide for time-  
12 ly review of, and action on, requests for a data  
13 use agreement under this subsection, taking  
14 into consideration the reasonable needs of the  
15 research center or organization.

16 “(D) PUBLIC DISCLOSURE.—The Sec-  
17 retary shall make available to the public the cri-  
18 teria developed under subparagraph (B)(i) that  
19 is used to grant or deny a data use agreement  
20 under this subsection.

21 “(5) FEEDBACK BY RESEARCH CENTER OR OR-  
22 GANIZATION.—

23 “(A) NOTIFICATION OF INACCURACIES DIS-  
24 COVERED IN DATA PROVIDED.—The Secretary  
25 shall establish procedures to ensure that a re-

1 search center or organization that is provided  
2 data under this subsection notifies the Sec-  
3 retary of any inaccuracies discovered in the  
4 data by the center or organization within a rea-  
5 sonable time of such discovery.

6 “(B) FEEDBACK ON DATA COLLECTION.—  
7 The Secretary shall permit researchers to pro-  
8 vide feedback on the collection of data with re-  
9 spect to the programs administered by the Cen-  
10 ters for Medicare & Medicaid Services and  
11 make recommendations with respect to the col-  
12 lection of additional data elements with respect  
13 to such programs.

14 “(6) CONFIDENTIALITY.—

15 “(A) DETERMINING APPROPRIATE LEVEL  
16 OF DATA TO BE PROVIDED.—The Secretary  
17 shall establish a process to determine the ap-  
18 propriate level of data to be provided to a re-  
19 search center or organization under this sub-  
20 section in order to ensure that the center or or-  
21 ganization, and researchers within the center or  
22 organization, are able to conduct meaningful  
23 analyses while maintaining the confidentiality of  
24 the data provided under the data use agree-  
25 ment.

1                   “(B) SAFEGUARDS TO PROTECT CON-  
2 FIDENTIALITY OF DATA PROVIDED.—

3                   “(i) IN GENERAL.—The Secretary  
4 shall establish safeguards to protect the  
5 confidentiality of data after it is provided  
6 to a research center or organization under  
7 this subsection. Such safeguards shall not  
8 provide for greater disclosure by the re-  
9 search center or organization than is per-  
10 mitted under any of the following:

11                   “(I) The Federal regulations  
12 (concerning the privacy of individually  
13 identifiable health information) pro-  
14 mulgated under section 264(c) of the  
15 Health Insurance Portability and Ac-  
16 countability Act of 1996.

17                   “(II) Sections 552 or 552a of  
18 title 5, United States Code, with re-  
19 gard to the privacy of individually  
20 identifiable beneficiary health infor-  
21 mation.

22                   “(ii) CONFIDENTIALITY OF PHYSI-  
23 CIANS AND MEDICAL PRACTICES.—The  
24 safeguards established under clause (i)  
25 shall ensure that the data provided to a re-

1 search center or organization under this  
2 subsection that identifies individual physi-  
3 cians or medical practices is not released  
4 by the research center or organization, or  
5 otherwise made public in a manner that  
6 identifies individual physicians or medical  
7 practices.

8 “(7) ACCESS BY CONTRACTORS AND SUB-  
9 CONTRACTORS.—In the case of a public or private  
10 entity that enters into a contract or subcontract with  
11 a research center or organization described in para-  
12 graph (2) to conduct activities for such research cen-  
13 ter or organization under this subsection, any access  
14 by such entity to data from the program under this  
15 title under this subsection shall be provided in ac-  
16 cordance with this subsection and subject to the  
17 same requirements as access for a research center or  
18 organization under this subsection.

19 “(8) REPORT.—The Secretary shall report to  
20 Congress on an annual basis (beginning with 2008)  
21 an evaluation of the agreements entered into under  
22 paragraph (1)(A), including a list and a description  
23 of the research conducted by research centers and  
24 organizations using data provided under such an  
25 agreement.

1           “(9) REASONABLE FEE.—The Secretary may  
2 charge a research center or organization a reason-  
3 able fee based on the cost of preparing and pro-  
4 viding data to such center or organization under this  
5 subsection.”.

6           (2) CRITERIA DEVELOPMENT AND PUBLICA-  
7 TION.—The Secretary shall develop and publish the  
8 criteria required under section 1860D–  
9 42(d)(4)(B)(i) of the Social Security Act, as added  
10 by paragraph (1), not later than 180 days after the  
11 date of enactment of this Act.