United States Senate Committee on Finance

For Immediate Release
Monday, September 18, 2006

Grassley, Baucus sponsor bill for research on effectiveness and safety of medical treatments

WASHINGTON — Sens. Chuck Grassley and Max Baucus have introduced legislation to improve the study of medical treatments, including the effectiveness and safety of drugs, by giving researchers at federal agencies and university-based and other research organizations highly controlled access to data on hospital, physician and prescription drug benefits that are provided to Medicare beneficiaries.

"This initiative is about improving the quality of health care by careful study of what is happening in the real world," Grassley said. "Medicare processes 500 million claims for benefits every year, and millions of prescriptions are filled through the new Medicare prescription drug benefit. Information about these benefits would be a tremendous resource for qualified health services researchers, and it would help them conduct rigorous studies on the safety and effectiveness of various medical treatments. Researchers could help us better understand why services that we know can help people maintain good health are not being used and to develop policies to promote their use, for example."

Grassley also said that before any information would be made available, "we would need to make sure that the strongest safeguards are in place to protect beneficiaries' and providers' privacy and confidentiality." He said that he and Baucus included several provisions to address that "extremely important issue."

"This bill will safely and efficiently turn the wealth of data held by Medicare into a powerful tool for improving America's health care system," said Baucus. "For the first time, a number of federal agencies will be able to work together to evaluate the care of a large segment of the population, and researchers will be able to analyze the safety and effectiveness of various treatments those patients receive. And this data will be used in a framework designed solely to promote the public good."

The Medicare Data Access and Research Act (S. 3897) would apply to the Food and Drug Administration, the Centers for Disease Control, the National Institutes of Health and the Agency for Healthcare Research and Quality. Researchers given access to information would be required to meet strict criteria, including significant expertise in analyzing the type and volume of data in question. They must also publish their methodology and findings, and they would be prohibited from selling the data or using it to create any commercial products. The researchers must have approval from a review board for the protection of human subjects which have exacting standards regarding the protection of identifiable information. They also must submit a data

management plan that details measures that will be taken to safeguard the data and to protect the privacy of any beneficiary. Provider-specific information could not be made public.

Grassley is chairman and Baucus is ranking member of the Senate Committee on Finance. A one-page summary of the new legislation, a section-by-section description, and the September 14 floor statements marking introduction by Grassley and Baucus follow here.

ONE-PAGE SUMMARY
THE MEDICARE DATA ACCESS AND RESEARCH ACT
INTRODUCED ON SEPTEMBER 14, 2006

ESTABLISHING PROCESSES FOR ACCESSING MEDICARE CLAIMS DATA

The Medicare Data Access and Research Act establishes a framework to permit the analysis of data on benefits provided to Medicare beneficiaries. Linking data on hospital and physician services provided to Medicare beneficiaries to prescription drug data creates a new resource for researchers to study drug safety and patterns of health care use among older adults and low-income, disabled and vulnerable populations. With appropriate protections for privacy and confidentiality, the Act makes this data resource available to federal agencies and permits university-based research centers and other research organizations to request access to the data. The agencies and researchers could use the data to conduct studies aimed at furthering the public's health through research on drug safety and patterns of health care utilization.

ADVANCING THE PUBLIC'S HEALTH AND SAFETY THROUGH HEALTH SERVICES RESEARCH

The data made available under the Act will provide federal agencies, including the Food and Drug Administration, Centers for Disease Control and Prevention, the Agency for Healthcare Research and Quality (AHRQ), the National Institutes of Health, and university-based research centers and other research organizations the opportunity to conduct in-depth analyses related to: post-marketing surveillance of prescription drugs; promotion of consumer and provider education about various treatments; development and use of preventive screening protocols; clinical comparative effectiveness; and prevention, detection, diagnosis, and treatment of diseases.

Information on research based on data attained under a data release agreement or data use agreement, including the methodology and results, will be made available to Congress and the public.

ENSURING THAT CONGRESSIONAL SUPPORT AGENCIES HAVE ACCESS TO NECESSARY DATA

The Act also ensures that Congressional support agencies, such as the Congressional Budget Office (CBO), the Government Accountability Office (GAO), and the Medicare Payment Advisory Commission (MedPAC), can access data necessary to fulfill their missions supporting work by Congress related to the Medicare program.

The Secretary must establish safeguards to protect the confidentiality of data released to

the Congressional support agencies. None of the data provided to the Congressional support agencies can be disclosed, reported or released in a form that permits the identification of a specific prescription drug plan, Medicare Advantage-Prescription Drug Plan, pharmacy benefit manager, drug manufacturer, drug wholesaler, or individual enrolled in a prescription drug plan or Medicare Advantage prescription drug plan.

SECTION-BY-SECTION SUMMARY
THE MEDICARE DATA ACCESS AND RESEARCH ACT

Title and Overview: The Medicare Data Access and Research Act establishes a framework to permit researchers at federal agencies and university-based research centers and other research organizations to analyze data on benefits provided to Medicare beneficiaries.

Section 2. Findings
– The Centers for Medicare and Medicaid Services collects substantial data on benefits provided to Medicare beneficiaries.
– Linking hospital and ambulatory care data to prescription drug data creates a new resource for the study of drug safety and patterns of health care use.
– Making these data available with appropriate privacy safeguards will enable federal agencies, including the Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), the Agency for Healthcare Research and Quality (AHRQ), and the National Institutes of Health (NIH), and university-based research centers and other research organizations to conduct studies to advance the public's health through research on drug safety and health care use.
– Allowing Congressional support agencies timely and ready access to these data also will enable them to fulfill their missions in informing and advising Congress on the cost, scope and impact of the new prescription drug benefit.

Section 3. Drug and Health Care Data Release
Release to Federal Agencies
– Requires the Secretary of Health and Human Services to enter annual data release agreements with the FDA, CDC, AHRQ, and the NIH.
– Data will include prescription drug benefit data linked to data on other Medicare benefits.
– Agencies will use the data solely to conduct studies on: post-marketing surveillance of prescription drugs; patterns of use over time, improving surveillance of clinical outbreaks and emerging threats, development and use of preventive screenings, clinical comparative effectiveness, quality, safety, efficiency and effectiveness of health care, and disease and disability prevention, detection, diagnosis and treatment.
– The Secretary must develop a process to protect the confidentiality of the data and to ensure that researchers can conduct meaningful analyses.
– On an annual basis, the Secretary must report to Congress on the types of studies conducted by agencies using the data.
– The Secretary will establish procedures to allow for feedback on data accuracy.

Release to University-Based Research Centers and Other Research Organizations

– Permits the Secretary to enter data use agreements with university-based research centers and other research organizations whose primary missions are to conduct research: (1) for purposes of providing generalizable knowledge to inform the public's health and (2) that coincides with the types of research that federal agencies can conduct.

– Data will include prescription drug benefit data linked to data on other Medicare benefits. Researchers will be permitted under a data use agreement to link these data to other relevant health data, including vital statistics and disease registries.

– A researcher who violates terms of the data use agreement will be subject to civil money penalties and disqualification from receiving any additional data for at least two years.

– The Secretary will establish and publish not later than 180 days after enactment criteria for approving a data use agreement. Criteria must include that the research center or other research organization: exhibit well-documented scientific expertise, demonstrate credible capability to conduct and complete the proposed study, demonstrate the proposed study's public health importance, establish a data management plan, express compliance with a requirement for publication of the results and methodology, receive approval from a review board, agree not to sell the data or to use the data to create commercial data products, and provide assurances of its independence.

– The Secretary will establish procedures to allow for feedback on data accuracy and recommendations regarding the collection of additional data elements.

– The Secretary must develop a process to protect the confidentiality of the data and to ensure that researchers can conduct meaningful analyses. The Secretary must also develop safeguards to protect the confidentiality of data after it is provided to the research center or organization. The safeguards shall prohibit disclosure by the research center or organization than is permitted under the Health Insurance Portability and Accountability Act of 1996 and must ensure that physician identifiable data is not released by the research center or organization.

– Allows the Secretary to charge a reasonable fee for preparing and providing data.

Section 4. Access to Data on Prescription Drug Plans and Medicare Advantage Plans

– The Secretary will provide data on the Medicare prescription drug benefit to Congressional support agencies (i.e., the Congressional Budget Office, Government Accountability Office, the Medicare Payment Advisory Commission, and the Congressional Research Service) that make official baseline spending projections, conduct oversight studies mandated by Congress, or make official recommendations on the Medicare program.

– Data to be supplied include aggregate negotiated prices for drugs covered under prescription drug plans and Medicare Advantage-prescription drug plans and drug event data submitted.

– Data provided to Congressional support agencies shall not be disclosed, reported, or released in a form that permits the identification of a specific prescription drug plan, MA-PD plan, pharmacy benefit manager, drug manufacturer, drug wholesaler, or individual.

– Establishes that MedPAC must examine factors that affect expenditures, payment methodologies, and their relationship to access and quality under the Medicare prescription drug benefit.

FLOOR STATEMENT OF U.S. SENATOR CHUCK GRASSLEY OF IOWA

CHAIRMAN OF THE COMMITTEE ON FINANCE
INTRODUCTION OF THE MEDICARE DATA ACCESS AND RESEARCH ACT
SEPTEMBER 14, 2006

Mr. President, I am pleased to join my colleague from Montana, Senator Baucus, in introducing the Medicare Data Access and Research Act. Senator Baucus and I have long enjoyed a good working relationship in our roles as Chairman and Ranking Member of the Finance Committee. Our work on this bill once again demonstrates our commitment to working in a bipartisan manner.

The Medicare Data Access and Research Act establishes a process through which federal agencies and other researchers can access Medicare data for the purpose of health services research. This might seem like a pretty mundane issue to some people, but I can assure you that it is far from it. Medicare processes five hundred million claims for benefits each year; millions of prescriptions have been filled under the new Medicare prescription drug benefit.

Linking data on hospital and physician services provided to Medicare beneficiaries to prescription drug data will offer a tremendous resource for researchers in our federal agencies, as well as those based at universities and other research centers. What type of research can these data support? They can support studies and analyses related to post-marketing surveillance of prescription drugs and research on drug safety. More concretely, analyzing the Medicare claims data can help agencies, such as the Food and Drug Administration (FDA), identify situations like the one involving Vioxx more quickly and provide a new valuable tool to enable the FDA to take swifter action to protect the public's health and well-being.

The Centers for Disease Control and Prevention, the Agency for Healthcare Research and Quality, and the National Institutes of Health all have missions that require the conduct of meticulous health services research. The Medicare database and access to it established under the bill we're introducing today will help these agencies fulfill their missions to study immunization rates; to develop and monitor the use of preventive screenings; conduct research on the clinical comparative effectiveness of prescription drugs; and to help prevent, diagnose and treat disease.

To ensure access to the data, the bill requires the Secretary of Health and Human Services to enter data release agreements on an annual basis with these agencies. In entering the data release agreements, the Secretary must take appropriate steps to protect the confidentiality of the information, while maintaining the ability of researchers at federal agencies to conduct meaningful analyses.

The bill also permits the Secretary to enter into data use agreements to permit researchers at universities and other organizations to have access to the data. As will be the case for the federal agencies, these researchers may only use the data for purposes of advancing the public's health. They can conduct studies on the safety, effectiveness, and quality of health services.

Some people might be concerned that these data will be given to just anyone. That is not

the case. In applying for data access, researchers at universities and other organizations will have to meet strict criteria. They must have well-documented experience in analyzing the type and volume of data to be provided under the agreement. They must agree to publish and publicly disseminate their research methodology and results. They must obtain approval for their study from a review board. They must comply with all safeguards established by the Secretary to ensure the confidentiality of information. These safeguards cannot permit the disclosure of information to an extent greater than permitted by the Health Insurance Portability and Accountability Act of 1996 and the Privacy Act of 1974.

The final section of the bill ensures that Congressional support agencies, including the Congressional Budget Office, the Congressional Research Service, the Government Accountability Office, and the Medicare Payment Advisory Commission, also have access to data they need to carry out their functions and responsibilities. This body depends on the research and analyses conducted by those agencies to inform our deliberations and decisions on the Medicare program.

Last year, Senator Baucus and I introduced the Medicare Value-Based Purchasing Act to establish a pay for performance system under Medicare. That bill was aimed at promoting quality and ensuring value under the Medicare program. The bill that we are introducing today complements that objective. How can we promote quality and ensure value in Medicare? By having a better understanding of what services are effective, by knowing how we can help beneficiaries avoid illness and disease, by having insight about potential over-use and under-use of health care services, and by identifying troubling trends and patterns. How can we learn about those topics? By supporting rigorous health services research.

FLOOR STATEMENT OF U.S. SENATOR MAX BAUCUS OF MONTANA
RANKING MEMBER OF THE COMMITTEE ON FINANCE
INTRODUCTION OF THE MEDICARE DATA ACCESS AND RESEARCH ACT
SEPTEMBER 14, 2006

MR BAUCUS: Mr. President, yesterday, I was pleased to join Chairman Grassley in introducing the Medicare Data Access and Research Act. This bill will take an important step to advance the safety, efficacy, and quality of health care services delivered to people under the Medicare program. And it will help improve the care delivered to all Americans.

This bill requires the Secretary of Health and Human Services (HHS) to make Medicare data accessible to federal health agencies and the health services research community for the purpose of conducting studies that will serve the public health. As the largest single payer of health care services in the United States-covering over 40 million lives, 70 million hospital days and processing nearly a billion physician claims per year-Medicare collects and maintains a wealth of information on the health services delivered to a significant portion of the population. This information has been a national resource for research and analysis of health care. And with the addition of the Medicare prescription drug benefit, it will be the most comprehensive resource our nation has to study the effects of diseases and the treatments we have for them.

The Centers for Medicare and Medicaid Service (CMS) currently releases certain Medicare data to the public and more comprehensive data to the research community. This bill would build on current activities by requiring CMS to link hospital claims, physician claims and other relevant information to data collected under the new Medicare drug benefit.

In addition, the Secretary will provide yearly access to the linked Medicare dataset to all federal health agencies within the department, such as the Food and Drug Administration, the Centers for Disease Control, the National Institutes of Health and the Agency for Healthcare Quality and Research. These agencies will enter into data use agreements with CMS to ensure that the type and level of Medicare data shared is appropriate, that the agencies conduct research in accordance with their missions and the purpose of furthering the public health, and that the privacy of the data is protected. The goal is to give federal health agencies another tool to evaluate the safety, efficacy and quality of care delivered to Medicare beneficiaries-a large segment of the health system.

This bill also provides public health researchers access to the linked Medicare dataset. Expanding access to Medicare data will open up a new era in our health system. It will enable scientists to more quickly identify both short and long-term safety concerns with drug regimens and health treatments. It will enable more treatments to be compared. And it will promote more development of guidelines, so providers and patients know more about what works best.

Some may argue that access to linked Medicare data should not be limited to researchers and should be available for commercial purposes. But the full Medicare database should be used exclusively for the public good, and not for private or commercial gain. This is the crux of this bill. Hence, the bill limits the use of data to the purpose of providing "generalizable knowledge to inform the public health through scientific publication and other forms of public dissemination." Strict penalties will be imposed on any unauthorized use of the data, including civil money penalties and disqualification from receiving Medicare data for at least two years.

CMS will publish criteria used to approve research applications to ensure that those selected are qualified and experienced to conduct analyses and maintain the confidentiality of Medicare information. Researchers will also make public their detailed results and methods within one year from completing their studies. They will make available to the public at no charge any tool developed through this program. They must agree not to sell data or create commercial data products using such data and abide by safeguards protecting the confidentiality of the data established by the Secretary.

The final section of the bill ensures that Congressional support agencies, including the Congressional Budget Office, the Congressional Research Service, the Government Accountability Office, and the Medicare Payment Advisory Commission, also have access to the full range of data they need to carry out their functions and responsibilities. Congress depends on the research and analyses conducted by these agencies to inform our deliberations and decisions on the Medicare program.

Last year, I worked with Senator Grassley to introduce the Medicare Value-Based

Purchasing Act, which establishes a pay for performance system under Medicare. An important element of that system is the collection and reporting of quality measures to CMS and to the public. The bill that we are introducing today complements those activities. We can improve health care by allowing Medicare to become a value-based purchaser of services and by reporting quality measures through the Medicare program. And we can improve health care for all by allowing rigorous health services research to be conducted using the resource of Medicare data.

Mr. President, the Medicare Data Access and Research Act will allow us to expand our knowledge of health care and improve the quality of care for all Americans.

I yield the floor.