United States Senate

Committee on Finance

Washington, D.C. 20510

For Immediate Release
Thursday, May 24, 2007

Grassley, Baucus bill would enhance research on pharmaceutical safety and effectiveness

WASHINGTON — Responding to growing concerns about the safety of pharmaceuticals, Sens. Chuck Grassley and Max Baucus introduced legislation today to improve the study of medical treatments, including the effectiveness and safety of drugs.

Their proposal would give 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.

"The situation that's unfolding this week with the popular diabetes drug Avandia emphasizes the value of making this sort of rich source of information available to experienced and credentialed researchers," Grassley said. "The drug trials that go on before the Food and Drug Administration approves a drug are no match for the wealth of information that's available after a drug is on the market and millions of people start taking it. This legislative initiative will tap that valuable information on behalf of public safety and public health. And, it does so in a way that makes sure the strongest safeguards are in place to protect privacy and confidentiality."

"Knowledge is power, and this bill will empower our health system to serve Americans better," said Baucus. "The secure and efficient sharing of Medicare's vast data among a number of Federal agencies will enable researchers to accurately examine the safety and effectiveness of many treatments patients receive. More eyes might have helped us spot a situation like we learned about just this week with the FDA's handling of the diabetes drug Avandia. This bill provides for this information-sharing with no other goal than to promote the public's health and the public good."

Medicare processes 500 million claims for benefits every year, and millions of prescriptions are filled annually through the new Medicare prescription drug benefit. Grassley said 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.

Grassley and Baucus said that researchers could help policy makers 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.

The Access to Medicare Data Act of 2007 is based on similar legislation, S.3897 – the Medicare Data Access and Research Act – that was introduced last September by Grassley and

Baucus. The provisions 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 Ranking Member and Baucus is Chairman of the Senate Committee on Finance, which is responsible for Medicare legislation and oversight.

The Access to Medicare Data Act of 2007
Introduced May 24, 2007
Section-by-Section Summary

Title and Overview: The Access to Medicare Data 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. Drug and Health Care Claims 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.
- Any contractor or subcontractor conducting research using Medicare data on behalf of a federal agency must enter a data use agreement with the Centers for Medicare and Medicaid Services.
- 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 for purposes of providing generalizable knowledge to inform the public's health.
- 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.
- Any contractor or subcontractor conducting research using Medicare data on behalf of a university-based or other research organization must enter a data use agreement with the Centers for Medicare and Medicaid Services.
- Allows the Secretary to charge a reasonable fee for preparing and providing data.
- On an annual basis, the Secretary must report to Congress on the types of studies conducted by university-based and other research organizations using the data.

Floor Statement of U.S. Sen. Chuck Grassley of Iowa
Introduction of the Access to Medicare Data Act of 2007
Thursday, May 24, 2007

Mr. President, I am pleased to join my colleague from Montana, Senator Baucus in introducing the Access to Medicare Data Act. This legislation is based on S. 3897, the Medicare Data Access and Research Act, which Senator Baucus and I introduced in the 109th Congress.

The bill we are introducing today establishes a framework under which federal agencies within the Department of Health and Human Services would have access to Medicare data, including data collected under the Medicare prescription drug benefit, to conduct research consistent with the agencies' missions. The legislation also creates a process through which university-based and other researchers who meet a strict set of requirements would be permitted to use Medicare data for research purposes.

As I said last year, Medicare data, particularly prescription drug data, are an immense

resource that can support critical health services research, especially research on drug safety. Examining Medicare data could help the FDA identify situations, such as the one involving Vioxx more quickly and to take quick action to protect the public's health and safety.

But the FDA isn't the only place that this important research can and should occur. The study issued earlier this week in the New England Journal of Medicine regarding the prescription medicine Avandia clearly demonstrates that point. Researchers from the Cleveland Clinic found that there are serious problems with Avandia – a drug that has been on the market for eight years and is used to treat diabetes. Specifically, the researchers believe that taking Avandia increases the likelihood that a diabetic patient will have a heart attack and maybe even die. The researchers came to this conclusion after reviewing information from forty-two clinical trials. Making Medicare data available to researchers like those at the Cleveland Clinic will offer another avenue for them to take in conducting research like this.

I want to be clear that, similar to last year's bill, the Access to Medicare Data Act won't permit just anyone to get the Medicare data. 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.

Mr. President, I am hopeful that we can get this bill approved soon. I, for one, don't want to be standing here next year talking about another Vioxx or another Avandia. We need to improve and create more opportunities for the government, as well as other researchers, to spot potential trouble with a drug more quickly and to take swifter steps to protect the public's health and safety. The Access to Medicare Data Act will help us accomplish that critical goal.

I yield the floor.