



October 2, 2007

Susan E. Dudley, Administrator
 Office of Information and Regulatory Affairs
 U.S. Office of Management and Budget
 Eisenhower Executive Office Building
 1650 Pennsylvania Avenue, NW
 Room 262
 Washington, DC 20502

Re: CMS-4119-P (42 CFR Part 23 “Medicare Program; Medicare Part D Data”)

On October 18, 2006, the Centers for Medicare and Medicaid Services (CMS) published “Medicare Program; Medicare Part D Data.” AcademyHealth, as the nonpartisan, professional society for nearly 3,800 health services researchers, policy analysts, and practitioners, welcomed the opportunity to submit comments (attached). We are seriously concerned that nearly a year later a final rule has yet to be published. We urge the Office of Management and Budget (OMB) to move quickly to promulgate the final rule.

The Medicare program covers 42 million elderly and disabled Americans and accounts for 17 percent of the nation’s total health care spending.¹ It is one of the largest federal programs and a vital part of the nation’s safety net for millions of aged and disabled beneficiaries. As Medicare’s steward, CMS has a critical fiduciary role in overseeing program efficiency and effectiveness and is legislatively empowered to request data that the agency considers necessary for planning, evaluation, policy development, and program administration. The agency’s fiduciary responsibilities underscore the importance of agency policies that foster Medicare research generally, as well as the creation of knowledge regarding Part D expenditures and operations, which in turn will help improve program performance.

Part D program data are essential, from a public health perspective, for responsible management of such a large program involving such substantial public investments and such important consequences for Medicare beneficiary health. Without the research that turns masses of data into knowledge, we would argue, CMS is unable either to carry out its legislatively mandated functions or to provide the data needed by other federal agencies—such as the Food and Drug Administration (FDA)—that will in turn generate knowledge that is essential to undergirding their respective oversight functions.

These data are also critical for studies of drug safety, comparative effectiveness, and treatment outcomes in the elderly population, which is often under-represented in pre-market clinical trials of new therapies. This need has been highlighted, for example, in the Institute of Medicine’s (IOM) report on drug safety in which the IOM emphasized the need to utilize observational data (e.g., Part D data) as part of a system of pharmacovigilance to identify less-frequent adverse outcomes that clinical trials are not powered to detect.

¹ CMS Office of the Actuary, 2005.

Recent developments, such as the controversy over the safety of Avandia and the passage of the FDA Amendments Act of 2007 (P.L. 110-85) have further highlighted the urgency of implementing the Medicare Part D data access rule. As you know, P.L. 110-85 requires the development of a post-market risk identification and analysis system to link and analyze data from multiple sources. Medicare data, as available, are among the sources cited to be used in this way for active adverse event surveillance. The Medicare Part D data are, indeed, essential for such analysis in the elderly population—a population that utilizes more than one-third of all prescription drugs—as no other data source is comparable in its size, power, and representativeness. Furthermore, the data are essential for studies of effectiveness and other outcomes in patient subpopulations that are often unrepresented or underrepresented in pre-marketing clinical trials, such as elderly persons with multiple co-morbidities. Until the regulation is promulgated, these data remain unavailable for these essential public health purposes.

Time is of the essence in this matter. Every month that passes where access to Medicare Part D data is restricted for research purposes—both within and outside federal agencies such as the FDA, National Institutes of Health, Agency for Healthcare Research and Quality, Centers for Disease Control and Prevention, and others—represents additional lost opportunities to generate the essential knowledge to inform the health care of our elderly and disabled populations.

For these reasons, it is critical that OMB promulgate the final rule and ensure that Part D data, like those for Part A and Part B of the Medicare program, are made widely available for both federally and privately funded research. Please do not hesitate to contact our government relations director, Emily Rowe (202.292.6743 or emily.rowe@academyhealth.org) or me with any questions.

Sincerely,



W. David Helms, Ph.D.
President & CEO

CC: The Honorable Max Baucus
The Honorable Chuck Grassley
The Honorable John D. Rockefeller IV
The Honorable Orrin G. Hatch
The Honorable Charles Rangel
The Honorable Jim McCrery
The Honorable Pete Stark
The Honorable Dave Camp
Kerry N. Weems, Centers for Medicare and Medicaid Services

Enclosure: AcademyHealth's comments on CMS-4119-P, 42 CFR Part 23, "Medicare Program; Medicare Part D Data"