



December 18, 2006

U.S. Department of Health and Human Services
Centers for Medicare and Medicaid Services
Attention: CMS-4119-P
PO Box 8017
Baltimore, MD 21244-8017

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

AcademyHealth, as the nonpartisan, professional society for nearly 3,800 health services researchers, policy analysts, and practitioners, welcomes the opportunity to respond to the regulations published October 18, “Medicare Program; Medicare Part D Data.” Given the implications of this rule on our mission, our members, and the research community, we strongly support the proposed regulations.

AcademyHealth views these and other regulations promoting the use of data for health services research as matters that are essential to the public good. We commend the Centers for Medicare and Medicaid Services (CMS) for proposing a rule that balances transparency and the use of analysis to support important public policy goals with the need to protect personal health information privacy as well as the proprietary concerns of private entities. We urge CMS to move quickly to promulgate a final rule.

At the same time, we remain concerned about the overall process for securing and using data in Medicare-related health services research, and we raise those concerns, where relevant, in these comments. Researchers often face difficulties gaining access to and using existing Medicare administrative data sets. Some of these difficulties may be the inevitable consequence of trying to conform data designed for program administration to research uses and applications. Other access challenges however appear to be the result of regulatory policies and administrative practices that impose additional and, in our view, unnecessary burdens unrelated to privacy, security, or other legitimate agency interests. We therefore recommend that as part of promulgating the final rule, CMS examine all relevant and general Medicare data release practices, in particular, your agency’s decision, as part of Part D program implementation, to eliminate files that have long been publicly available (e.g. the monthly Geographical Service Area and quarterly Market Penetration Report Files). Both sets of data have a long history of public availability, and researchers and industry officials alike have long used these data to monitor Medicare Advantage and its predecessor programs. These files have been replaced with more limited files that are much less useful for this purpose. In an era of data transparency and a growing bi-partisan emphasis on comparative effectiveness research, AcademyHealth therefore

recommends that CMS evaluate its relevant data access policies generally and looks forward to supporting such an effort.

The Importance of Transparency and Use of Data in Research

The Medicare program covers 42 million elderly and disabled Americans and accounts for 17 percent of the nation's total health care spending.¹ Medicare 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. We therefore strongly agree with CMS' conclusion in the proposed rule (Part II.B) regarding the critical nature of Part D data in meeting the agency's fiduciary responsibilities and administration functions. For example:

- Part D data could help inform the agency's regulatory standards for formularies. Current regulatory guidelines include a provision that formularies must include "most or all" drugs in selected drug classes. Yet some versions of these drugs may not be covered, since plans may apply restrictions (e.g., prior authorization) or non-preferred status to the covered drugs in these classes. With Part D data, research can analyze utilization patterns in protected classes and see whether the use of restrictions, the higher cost for non-preferred drugs, or the excluded variants restrict beneficiaries' access.
- Part D data could allow the agency to measure the success of prescription drug plans in encouraging the use of generic drugs. CMS has released aggregate generic dispensing rates, but cannot tell from these aggregate rates how many of the prescriptions filled with brand-name drugs in fact had generic alternatives. Such a determination will be possible using Part D claims data. Since there is broad agreement that higher use of generic drugs can benefit beneficiaries and taxpayers, research on what measures best encourage higher generic rates can help the agency encourage best practices from drug plans.

In short, 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 FDA, that will in turn generate the knowledge base that is essential to undergirding their respective oversight functions.

For these reasons, AcademyHealth fully supports CMS's rationale for the proposed rule and its intent: to ensure that Part D data, like those for Part A and Part B of the Medicare program, are made widely available for research. This research includes both

¹ CMS Office of the Actuary, 2005.

federally-funded research carried out by CMS or other public agencies whose responsibilities either bear on, or are affected by, Medicare coverage of prescription drugs, and privately-funded research projects (as the term “research” is used in the Common Rule) under which researchers agree to comply with all applicable privacy, security, and human subject protection standards. Such protections include releasing only the minimum data needed to complete the study, keeping beneficiary and provider identifiers confidential, and ensuring that Part D claims data are used for “legitimate research purposes.” AcademyHealth believes that the existing protocols and process have generally served all stakeholders well, prevented data misuse, and ultimately protected privacy.

Specific Provisions

Section B: Purpose of CMS Collecting Information

CMS describes a variety of needs for Part D data. CMS historically analyzes data both internally and through contracts and grants. We are assuming CMS intends that these rules cover both types of research, as well as research that, while funded by a source other than CMS, is being undertaken to advance general knowledge and not for proprietary purposes. The scope of the rule and its purposes should be clarified in the final rule (as described in Section C2).

Section C1: Sharing Data with Other Government Agencies

As noted, we strongly agree that Part D data are critical to CMS’s ability to discharge its program functions and that CMS’s needs require that data access extend beyond the limits of the programs over which it has direct administrative authority. For example, CMS has a direct interest in questions relating to drug safety, drug effectiveness, or the impact of coverage on public health threats. These research questions, however, most likely fall within the administrative purview of other federal agencies such as the FDA, the CDC or AHRQ. We therefore strongly support CMS’s intent to provide data access to research funded by or conducted under the purview of other public agencies such as HHS agencies (AHRQ, ASPE, CDC, FDA, NIH, the IHS, HRSA, SAMHSA, the OIG), the GAO and CBO.

We also recommend that access to data be extended to other agencies that administer federal health care programs such as the VA and the DoD. For example, the Department of Veterans Affairs (VA) requires access to these claims data to research and evaluate veterans’ health care; many veterans have recently enrolled in Medicare Part D and use the VA pharmacy for all or some of their medication purchases. CMS should seriously consider giving access to other public programs such as state Medicaid agencies or state pharmacy assistance programs. Therefore, we recommend that CMS give serious consideration to expanding this section to encompass most if not all publicly financed or administered health care programs.

Section C2: Sharing Data with External Researchers

We strongly support CMS’s interest in making data available for research. We support CMS’ desire to populate a chronic condition data warehouse (CCW); we recommend that CMS clarify that such warehouse would be available for any

research related to quality improvement, health care costs, and other purposes that bear on population health and health care. To make these data most useful, researchers may need to know more about the particular Medicare coverage in effect for each beneficiary over time. We therefore recommend that files created for this warehouse include information for each relevant time period on: (1) the plan enrollment status of each beneficiary (e.g., a prescription drug plan (PDP) or a Medicare Advantage prescription drug plan (MA-PD)); (2) the specific contract/plan identification number; and (3) gaps in claims history resulting from beneficiaries' receipt of Medicare Part A and B services through MA plans; currently, when beneficiaries' are enrolled in MA plans, their utilization of Part A and B services becomes a black box. Personal identifiers will allow researchers to merge publicly available data on PDP/MA-PD benefits to use and expenditure files. Methods for protecting the privacy and security of the data exist that would permit CMS to maintain such unique identifiers while simultaneously ensuring protections through data use agreements and data management protocols. For example, even if CMS does not release another file with benefits and premiums that is linkable to Part D, the agency could append some of the variables directly so that researchers do not have to make the link. We also recommend that CMS incorporate into the file relevant information regarding the receipt of a low income subsidy (LIS), and, if so, the type of coverage (including state Medicaid and, if possible, State Pharmaceutical Assistance Program coverage). This information will help researchers to account, as fully as possible, for other sources of financial support that might influence use and spending patterns.

The knowledge potential of Part D data depends not just on linking it to Parts A and B, but also on the ability to link Part D with a broad range of other data sources such as disease registries, birth and death records, and other data. When linked to these and other datasets, the availability of Medicare Part D data for research presents a vitally important opportunity to improve the public health of beneficiaries by expanding the knowledge base on outcomes, safety, adherence, disparities, and other aspects of drug use among the elderly and disabled. It is essential that consistent with its practices with respect to other data, CMS allow researchers to link Part D data with other data sources, under a protocol reviewed and approved by the CMS privacy board. The types of linkages that may be scientifically compelling cover a broad range, and it is not possible to predict all possible linkages that would advance knowledge. Therefore, we recommend that linked data research can be carried out by any research program that meets CMS standards for privacy, security, and the protection of human subjects. Linked research should not be restricted to those already existing linkages developed by CMS or its contractors. Such linkages are complex, vary across data types, require access to identifiable non-CMS data, and require close involvement of the researchers.

In addition to access to the most detailed data, we also suggest that CMS consider developing designated public use files with a smaller set of related variables that external researchers could use to conduct quality research for less money than likely would be required to create more comprehensive databases from the files CMS would otherwise make available. This could be similar to the chronic condition data warehouse described above; perhaps with fewer variables, but more representative data on beneficiaries as a whole. Such access also could reduce the

time delays in approving external requests for data access because it would triage requests in a way that might reduce the burden on CMS staff.

In making available data to external researchers (or others), we urge CMS to evaluate with caution requests that certain kinds of data be excluded from the files because of proprietary concerns. With respect to the issue of proprietary interest in data, we believe that there is confusion regarding *first*, the circumstances under which data related to a publicly-financed program will be considered proprietary, and *second*, if it is, the circumstances under which even proprietary data can be accessed and used for research, as long as proper research protocols are followed. The U.S. health care system is a market-based one, and as such, proprietary considerations are strong. At the same time, in such a system it is possible to argue that nearly all data related to enrollment, expenditures, pricing, use, and costs should be proprietary.

Assuming that at some point a legitimate proprietary interest does attach—even in the case of federally funded health care programs—proprietary status alone should not be sufficient to deter research falling within the federal definition of the term. The crucial policy balancing responsibility is to determine (1) the point at which data related to public programs should be considered proprietary either as a matter of law or policy; and (2) what additional safeguards against disclosure should apply when proprietary data are to be used in research. We strongly recommend that the Department as a whole establish a Department-wide process for reviewing and developing such a policy.

We similarly discourage additional requirements beyond those that now apply to Medicare Part A and Part B data. The providers and suppliers that have a direct stake in A and B payments clearly could assert a proprietary interest in shielding information about financing. While the legal structure of Part D is quite different, the underlying concerns flow from market interests. The experience of our members is that the requirements now in place at CMS provide substantial protections. We further urge CMS to avoid duplicating general protections already in place as a result of HIPAA and other federal requirements.

Thank you for the opportunity to submit these comments. We look forward to working with CMS to finalize and implement the proposed rule, and address our broad, data access concerns in the future. We realize that establishing this important new data infrastructure will be resource-intensive. We'd be happy to work with you on ways to increase CMS's ability to carry out these important new functions. 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