1101 Pennsylvania Avenue
Suite 600
Washington, DC 20004-2514
202.756.2227
202.756.7506 [fax]
www.accp.com

Department of Government & Professional Affairs

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

Reference File Code: CMS-4119-P

Dear Sir or Madam:

The American College of Clinical Pharmacy (ACCP) appreciates the opportunity to comment on the proposed rule published in the Federal Register on October 16, 2006, that would allow the Health and Human Services (HHS) Secretary to use claims information that is now being collected for Part D payment purposes for other research, analysis, reporting, and other public health functions.

ACCP is a national professional and scientific society representing almost 10,000 clinical pharmacist practitioners, researchers and educators. Our members have been among the profession's leaders for almost three decades in developing and providing professional services, consultation, cutting-edge clinical research, and education programs that improve the quality of medication use in the health care settings in which they practice.

It is clear that using claims information already being collected for Part D payment purposes from Part D plan sponsors for purposes other than those related to payments will facilitate better evaluation of the Medicare Part D prescription drug benefit, and better assessment of the impact and effectiveness of Part D expenditures on the overall Medicare program and other government sponsored health programs such as Medicaid or SCHIP. Crucially, these data must be linked at the individual beneficiary level to Part A and Part B claims data in order to determine how the Part D benefit affects broader beneficiary utilization of Medicare program services.

Clear Authority to Analyze Part D Data Can Improve Quality of Care for Medicare Beneficiaries

ACCP recognizes the importance of appropriate analysis of Part D data in order to report to Congress and the public on the overall statistics associated with the operation of the Medicare

Part D benefit, to conduct evaluations of the program, to make and respond to legislative proposals pertaining to Part D and other programs the agency administers, and to develop demonstration projects or other evaluations aimed at improving the economy, efficiency and effectiveness of the Medicare program.

Specifically, the proposed rule would allow a number of government oversight agencies including the Office of the Inspector General (OIG), the Government Accountability Office (GAO), the Congressional Budget Office (CBO), and the Medicare Payment Advisory Commission (MedPAC) access to Part D data to evaluate the cost effectiveness of various policies under the Part D program, evaluate spending on various classes of drugs and to analyze brand-name versus generic prescribing trends.

One of ACCP's core functions is to advance human health and quality of life through research and subsequent practice improvements and as such we strongly support the provision in the proposed rule that would authorize entities outside of CMS to access Part D data.

Medicare Part D Population Considerations

The Medicare Part D population represents unique population demographics which are not usually studied in clinical trials, including older patients, patients with multiple co-morbid diseases and people with a disability. These populations are more likely to experience adverse drug events than other populations, due to their age, relative poor health and because they typically take multiple medications for chronic diseases.

Section 723 of the Medicare Modernization Act (MMA) requires the HHS Secretary to develop a plan to "improve the quality of care for chronically ill Medicare beneficiaries." We are pleased to note that the proposed rule made reference to the creation of a "chronic care data warehouse" (CGW) that would be accessible to private researchers. Some of ACCP's members are well positioned and capable of playing a key role in analyzing and evaluating the utilization of medications under the Part D program, overall expenditures on the Part D program, and how levels of utilization and expenditure impact beneficiaries' therapeutic outcomes, as well as Medicare Part A and Part B, Medicaid, SCHIP and other expenditures. By developing this chronic care database, ACCP believes that CMS can make important steps towards improving the quality of and reducing the cost of health care services.

Identifying and Overcoming Health Care Disparities

One of the greatest challenges in health care delivery is ensuring a consistent level of quality and access to care to all patients nationwide. Because of the unique demographics of the Part D population, the proposed rule on Medicare data represents an opportunity to assess the magnitude of health disparities across geographic or patient demographic lines and in doing so evaluate broader public health issues and identify differences and possible remedial problems with the health care system.

Developing Best Practices for Medication Therapy Management Services (MTMS)

In the final rule implementing the MMA, CMS noted that MTMS must "evolve and become a cornerstone of the Medicare Prescription Drug Benefit." As Medicare Prescription Drug Plans

(PDPs) and Medicare-Advantage Prescription Drug Plans (MA-PDs) continue to develop MTM programs, it is clear that all Medicare stakeholders, including providers of MTMS, payers, beneficiaries and Medicare program administrators need access to data and reports evaluating the effectiveness of MTMS programs and illustrating their impact with regards to clinical outcomes and non-drug health care expenditures.

Evaluating the Impact of Step-Therapy
ACCP supports the development of cost-effective drug utilization management programs such as step-therapy in order to control costs and minimize risks. In order to evaluate the effectiveness of step therapy in achieving these stated outcomes, it is vital that CMS have the ability to evaluate and monitor both costs and health outcomes.

Drug Usage as a Surrogate Measure for the Existence and Severity of Diseases
In the proposed rule, it is noted that Medicare Part D data could be used by the National Institutes for Health (NIH) to investigate the incidence and prevalence of particular diseases, disease progression, and the health outcomes of people with the diseases. However, it is critical that in using drug usage as a surrogate measure for the existence and severity of diseases, NIH must be confident that the utilization of these drugs is appropriate, that the drugs are working and that they are not interacting with other drugs in such a way to negate their positive effects or have an unintended negative consequence.

Since 1997, 1) more than 250 new drugs were approved by the Food and Drug Administration (FDA), 2) the Institutes of Medicine (IOM) released two important reports on issues of preventable errors and needed changes in health care systems, and 3) expenditures on drugs increased by an average of 17% per year. Accordingly, in order for NIH to make informed and appropriate decisions based on drug usage statistics, it is vital that external researchers (including ACCP members) have access to data and can evaluate and analyze drug utilization and outcomes to ensure appropriate and safe usage of medications. Without this, NIH could base their reporting on outcomes that are the result of ineffective or unsafe medication utilization, rather than actual disease patterns.

In summary, ACCP recognizes the importance of clarifying that CMS has full authority to use claims information that is now being collected for Part D payment purposes for other research, analysis, reporting, and other public health functions. In addition, we commend the agency for recognizing the role that entities outside of CMS (including other government agencies and external researchers) can play in analyzing data and conducting studies to improve public health:

- To analyze Part D data and monitor a vulnerable population for medication-related issues and plan practices that may result in adverse drug events.
- To allow CMS to fulfill a requirement of the MMA by populating a chronic care data warehouse accessible by external researchers
- To identify and address nationwide health care disparities within the Medicare Part D population
- To help develop models and best practices for MTMS

- To assess the impact and effectiveness of tier structure and plan restrictions such as prior authorization, step-therapy and quantity limits
- To help ensure that drug usage data used to measure the existence and severity of diseases accurately reflect the incidence and prevalence of diseases rather than simply the inappropriate use of medications.

ACCP and its members welcome the opportunity to access and analyze Medicare Part D data for other research, analysis, reporting, and other public health functions in order to help evaluate the Medicare Part D prescription drug benefit, to assess the impact and effectiveness of expenditures under Part D and formulate and propose changes or developments affecting the Medicare program and other government sponsored health programs such as Medicaid or SCHIP. Please feel free to follow up with us at any time.

Sincerely,

Michael S. Maddux, Pharm. D., FCCP
Executive Director

C. Edwin Webb

C. Edwin Webb, Pharm. D., M.P.H.
Director, Government & Professional Affairs

Cc: ACCP Board of Regents

American College of Clinical Pharmacy • 3101 Broadway, Suite 650 • Kansas City, Missouri 64111-2446 • 816.531.2177
Michael S. Maddux, Pharm.D., FCCP, Executive Director