ACP
American College of Physicians
internal medicine | *Doctors for Adults*

December 18, 2006

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-4119-PPO Box 8017
Baltimore, MD 21244-8017

Re: Comments on the Centers for Medicare and Medicaid Services
Proposed Rule "Medicare Program; Medicare Part D Data," 71 Fed. Reg. 61445 (October 18, 2006)

Dear Ms. Norwalk:

The American College of Physicians, representing 120,000 physicians who specialize in internal medicine and medical students, appreciates the opportunity to submit comments on the Centers for Medicare and Medicaid Services (CMS) proposed rule, entitled "Medicare Program; Medicare Part D Data" published October 18, 2006 in the Federal Register.

As the largest medical specialty society and the second largest medical organization in the United States, the College is in a unique position to comment on the sharing of Medicare Part D claims data: our membership represents a wide-range of interests in internal medicine, including general internists and sub-specialists engaged in the practice of internal medicine as individual practitioners, members of group practices of all sizes, government employees, professors of medicine and medical researchers.

GENERAL COMMENTS

The College appreciates the efforts of CMS to ameliorate the fragmentation of Medicare population data by linking Part D information to other claims data, thus creating a more comprehensive data set. The College supports the reporting and evaluation of drug use within the Medicare prescription drug program, and the interaction between prescription drug coverage and services utilization under other Medicare programs. The College also recognizes the necessity of conducting claims data operations and studies to oversee the Medicare program, protect the public health, and respond to Congressional mandates. Moreover, the College believes that CMS, by engaging in this rulemaking, has resolved statutory ambiguity regarding the broad authority of section 1860D-12(b)(3)(D) of the Medicare Prescription Drug, Improvement and Modernization Act.

However, the College is concerned that CMS has not yet adequately addressed the potentially profound implications of expanding access to physician and patient information. If unique identifiers, provider prescribing patterns, and medication utilization information are shared in claims data, there could be substantial consequences for physician practices, performance

measurement programs and reimbursement formularies. The College is also concerned about potential marketing abuses if patient utilization and physician prescribing data are made available to external, non-governmental entities.

SPECIFIC COMMENTS

Purpose of CMS Collecting Information

Prescriber Information (II.B.4.d)

As a proponent of raising the quality of patient care, the College supports the concept of using Medicare Part D claims data for performance and quality improvement mechanisms to obtain better medical outcomes. However, the proposed rule must be modified to specify more clearly the conditions under which this physician data can be collected and used in performance programs, research studies, and demonstration projects. The College continues to be concerned with the burden placed on physicians to comply with multiple reporting forms, and encourages CMS to work with the private sector to minimize duplicative reporting requirements and to develop standardized reporting forms.

The College believes the goal of physician performance measurement should be to foster continuous quality improvement of clinical care that meets or exceeds evidence-based national standards of such care. Performance measures should assess and focus on elements of clinical care over which physicians have direct and instrumental control. To support performance measurement and reporting, effective data sharing requires the following:

- Transparency with respect to framework, process, and rules. Measures and methods for scoring and ranking performance should be as transparent as possible so that users and those being measured know results are valid and reliable

- Standardized and uniform rules associated with measurement and data collection.

- A process that facilitates making the data useful for physicians to improve the quality and cost of care they provide to their patients, and other appropriate purposes

- Compliance with privacy, confidentiality and other applicable rules, while ensuring that providers, plans, allied healthcare businesses, appropriate private/public entities, and consumers have necessary and appropriate access to useful information.

- Disclosures of physician-specific performance data only after participating physicians are provided an opportunity to review and comment on such data.

ACP
American College of Physicians
internal medicine | *Doctors for Adults*

Sharing Data with Entities Outside of CMS (Proposed § 423. 505.f.5)

Other government agencies (II.C.1)
The College considers it critical that provisions dealing with research use of Part D claims data recognize the delicate balance between protecting patient privacy and expanding our knowledge of health, disease, and of systems improvement mechanisms. The College supports the sharing of Part D claims data with other government research bodies, such as the Agency for Healthcare Research and Quality, Food and Drug Administration, and National Institutes of Health. Access to this data by these agencies is consistent with their missions to improve the public health, enhance the administration of health care, and promote more efficient health care financing.

External Researchers (II.C.2)
The College feels strongly that aggregated physician prescribing information should only be released to non-governmental entities with significantly clearer safeguards than currently proposed in this rule, and encourages CMS to consider additional regulatory limitations for external researchers beyond existing data use agreement protocols. Such provisions are necessary in order to further guard against the potential misuse of data for non-research purposes, commercial purposes, and to ensure that identifiable physician prescribing data, proprietary plan data, and confidential beneficiary data are not released.

As currently proposed, Part D data claims sharing could allow for marketing of "health-related" solicitations by other entities in the healthcare system. An external researcher could be affiliated with a drug company that seeks to identify and select patients based on their health information, or physicians based on their prescribing patterns. The drug company could send patients materials encouraging patients and physicians to switch their prescriptions to the drug company's particular brand of medicine. In addition, a list of patients with certain diagnoses could be shared with a disease management company so that certain products or therapies could be promoted.

Beneficiary Access to Part D Data and Personal Health Records (II.D)

The College supports the use of personal health records (PHRs) by CMS as one mechanism of creating patient-centric repositories of clinical information. However, the proposed rule does not provide enough detail regarding the development of PHRs, or the protection of patient health information. The College has long recognized the need for appropriate safeguards to protect patient privacy, because trust and respect are the cornerstones of the patient-physician relationship and to quality health care.

The College believes that PHR data should be in a structured format that uses standardized medical terminology appropriate for a typical patient's comprehension. Beneficiaries should be able to access their health and medical data conveniently and affordably, and should receive easily understood information about all the ways that their health data may be used or shared.

ACP
American College of Physicians
internal medicine | *Doctors for Adults*

The College also recognizes that patients have a basic, fundamental right to privacy that includes the information contained in their own medical records. PHRs should be secure and adhere to all current privacy and security standards. Clinical information and guidance provided by CMS should comply with the relevant URAC standards for web-based clinical content (http://www.urac.org/consumer_standards.asp)

The College believes that beneficiaries should be able to review which entities have access to their personal health data, and should have the option of providing different levels of access to their PHRs for specific users. Beneficiaries should be able to refuse to make their health data available for sharing (i.e. opt out), and to designate someone else, such as a loved one, to have access to and exercise control over how their PHRs are shared. Additionally, the College feels strongly that PHR data shared with entities other than the individual patient should be released only in an aggregate format, without any physician identifiers.

Applicability

The proposed rule states that it does not affect the applicability of HIPAA to the Department of Health and Human Services or any other appropriate parties. Claims data use agreements will still be required in accord with HIPAA requirements to obtain patient and prescriber information. Nevertheless, the College is concerned with the over-reliance of CMS on data use agreements to protect the use and disclosure of linked and identifiable patient and prescriber Medicare Part D data. Currently under HIPAA, data use agreements are for limited data sets, and do not address the expanse of Medicare Part D claims data. The College strongly suggests that the proposed rule be modified to include clear guidance regarding HIPAA and the sharing of claims data, particularly the protection of prescriber information.

The College urges CMS to reconsider the Medicare Part D Data Rule in light of our concerns and suggestions, and to publish an interim final rule that more fully addresses the issues we have raised. Again, the College appreciates the opportunity to offer comments on this important rule, and looks forward to working with you in the future. If you have any questions regarding our comments, please do not hesitate to contact Sara Hogan, Health Policy Analyst at (202) 261-4587, or Brett Baker, Director of Regulatory and Insurer Affairs at (202) 261- 4533.

Jeffrey P. Harris

Jeffrey P. Harris, MD, FACP
Chair, Health and Public Policy Committee