C. Sharing Data With Entities Outside of CMS (Proposed Sec. 423.505(f)(5))

In addition to collecting claims data for use in administering the Medicare Part D program under the authority of section 1860D-12(b)(3)(D) of the Act, CMS also believes that it is in the interest of public health to share some of the information collected under that authority with entities outside of CMS. As stated above, when information is collected under the authority of section 1860D-12(b)(3)(D) of the Act, we do not believe that the statutory language in section 1860D-15(d) and (f) of the Act (requiring the information collected under the authority of that section to be used only in implementing such section) would apply, since any initial collection would be effectuated outside of section 1860D-15 of the Act. Therefore, we are proposing to add Sec.423.505(f)(5) that would specify that we could use and share the claims information we collect under Sec. 423.505(f) with both outside entities and other government agencies, without regard to any restriction included in Sec. 423.322(b).

1. Other Government Agencies

In particular, Department of Health and Human Services' public health agencies such as NIH, FDA, and AHRQ have researchers that would also need to use Medicare Part D prescription drug related data for studies to improve public health consistent with the missions of these agencies. These studies will assess outcomes, and investigate clinical effectiveness, appropriateness of health care items and services (including prescription drugs), and develop strategies for improving the efficiency and effectiveness of clinical care. In addition, we believe that oversight agencies, such as the OIG, GAO, and CBO would need access to both aggregated and nonaggregated claims data in order to conduct evaluations of the Part D program. The NIH would need access to Medicare Part D data, linked to data from Medicare Parts A and B, in order to address its mission of conducting and supporting research regarding the cause, diagnosis, prevention, and cure of human diseases in order to improve the health of the nation. A wealth of information about diseases and their treatments can potentially be obtained from observational studies of therapeutic drug usage in Medicare patients. Because drug usages can be used as a surrogate measure for the existence and severity of diseases, Medicare Part D data could be used to investigate the incidence and prevalence of particular diseases, disease progression, and the health outcomes of people with the diseases, trends in disease and their treatments, and even the relative effectiveness of alternative therapeutic approaches. Moreover, matching Part D claims data with the Surveillance Epidemiology and End Results (SEER) cancer registry would enable additional studies of cancer treatment and outcomes. Given the large number of patients involved, studies could also be designed to identify comorbidities that would be undetectable in conventional, prospective cohort studies. In addition, studies that correlate drug prescribing patterns with geography or patient demographics or examine trends over time could be used to identify differences and possible remediable problems with the health care system, to assess the magnitude of health disparities related to the delivery of care and indirectly assess the impact of new medical findings and other influences on prescribing and other health care practices.

We also propose to share the information collected under the authority of section 1860D-12(b)(3)(D) of the Act with the FDA. The FDA's mission includes a mandate to ensure
the safety and efficacy of drugs for the American people. Patients age 65 and older are more likely to experience serious or fatal adverse drug events than younger individuals because of their generally poorer health and because they typically take multiple medications for chronic conditions, which increases their opportunity for experiencing adverse drug effects. Part D data could be used to monitor patterns of drug use in the elderly and the disabled with the goal of identifying unsafe or suboptimal patterns of use, either with respect to the particular types of drugs being used or with respect to the dose or duration of use of these drug products. Additionally, Part D data could be used to identify rare but serious complications that certain patients may have with drugs more quickly and effectively than is achieved with the current surveillance systems. Formal epidemiologic studies could also be performed, to examine the nature and magnitude of risk conferred by particular medications, to identify risk factors for adverse event occurrence, or to assess the effect of risk management programs intended to reduce prescription drug risks.

A third agency we believe would need access to the Part D claims data is the Agency for Healthcare Research and Quality (AHRQ). AHRQ's mission to conduct health services and outcomes studies in assessing the effectiveness of health care items and services, improving the quality of health care, promoting efficiency and patient safety, and reducing medical error will be enhanced by access to Medicare Part D claims data. Section 1013 of the MMA requires AHRQ to conduct research, demonstrations, and evaluations designed to improve the quality, effectiveness, and efficiency of Medicare, Medicaid, and the State Children's Health Insurance Program. To implement section 1013 of MMA, AHRQ has established a new research initiative called the Effective Health Care (EHC) program. The EHC program supports research on the outcomes, comparative clinical effectiveness, and appropriateness of pharmaceuticals, devices, and health care services. Included in the EHC program is a research network of 13 centers with over 60 affiliated health scientists and the capacity to—

1) scientifically analyze administrative, survey, and clinical databases;
2) develop and apply new scientific methods, instruments, and methodologies; and
3) operate and analyze computerized surveillance and monitoring systems.

The availability of Medicare Part D data, linked to data from Medicare Parts A and B, would greatly enhance the capacity of the EHC program to carry out research and program evaluations designed to improve the quality of CMS programs as mandated in section 1013 of the MMA.

Other agencies within DHHS, such as the Centers for Disease Control and Prevention, the Health Resources and Services Administration (HRSA), or the Office of the Assistant Secretary for Planning and Evaluation, may also need the prescription drug data to perform evaluations or assess policies.

We believe oversight agencies may also require access to the Part D claims data. These agencies would include the Office of the Inspector General (OIG), the Government Accountability Office (GAO), the Congressional Budget Office (CBO), and the Medicare Payment Advisory Commission (MedPAC). We believe these agencies may require access to data in order to evaluate the cost-effectiveness of various policies under the Part D program, to evaluate spending for various classes of drugs under such program, to analyze brand-name versus generic prescribing trends, and to conduct other oversight activities that are not specifically related to payment. For these reasons, we believe it would be appropriate to share some Part D data with these oversight agencies.

Given these necessities, we propose to allow broad access for other agencies to our Part D claims data linked to our other claims data files. Other agencies, including the agencies listed above, would enter into a data use agreement, similar to what is used today (and described in greater detail in section II.C.2). This would allow the sharing of event level cost data, however, through a data use agreement we would protect confidentiality of beneficiary information and ensure that the use of Part D claims data serves a legitimate research purpose. We would also ensure that any system of records with respect to claims data is updated to reflect the most current uses of such data. We
request comments on this proposed rule that would help us in our efforts to improve knowledge relevant to the public health. Specifically, we request guidance on how we can best serve the needs of other agencies through the sharing of information it collects under section 1860D-12(b)(3)(D) of the Act while at the same addressing the legitimate concerns of the public and of Part D plans that we appropriately guard against the potential misuse of data in ways that would undermine protections put in place to ensure confidentiality of beneficiary information, and the nondisclosure of proprietary data submitted by Part D plans.

2. External Researchers

External researchers, such as those based in universities, regularly request and analyze Medicare data for their research studies, many of which are designed to address questions of clinical importance. We believe researchers who study a broad range of topics need access to the Part D claims linked to Parts A and B claims data as well. The research questions that have been previously addressed through analyses of Parts A and B claims have contributed to very significant improvements in the public health, have been critical in assessing the quality of care and costs of care for patients in the Medicare program, and have in many cases spurred other types of research. As such, we believe that a data source that includes Parts A and B claims as well as their attendant Part D claims would be used in a similarly constructive manner, such that greater knowledge on a range of topics, both clinical and economic, will be generated. This knowledge is expected to contribute positively to the evaluation and functioning of the Medicare program, and to improve the clinical care of beneficiaries.

We will specifically address the needs of a segment of external researchers as part of our implementation of section 723 of the MMA, which requires the Secretary to develop a plan to ''improve the quality of care and reduce the cost of care for chronically ill Medicare beneficiaries.''

Congress specifically stated that the plan should provide for the collection of data in a data warehouse (see section 723(b)(3) of the MMA). We will implement section 723 of the MMA by populating a chronic care condition data warehouse (CCW) which would be accessible by private researchers in order for such researchers to conduct studies related to improving quality and reducing costs of care for chronically ill Medicare beneficiaries. The CCW will include a beneficiary sample and will include Part D claims, in order to allow researchers to analyze prescription drug information. In this way, researchers would be able to receive a complete picture of a beneficiary's care, and determine whether the treatment of chronically ill beneficiaries (including Parts A, B and D treatment) is as effective and efficient as possible.

In addition to the section 723 of the MMA data warehouse, we are planning to make available Medicare Part D claims data linked to other Medicare claims files to external researchers on the same terms as other Medicare Parts A and B data are released today, with appropriate protections for beneficiary confidentiality. These data would be disseminated under our standard data use agreement protocols. This means that each data request would be evaluated to determine whether--

1) A legitimate research purpose is presented by a responsible party,
2) The minimum data needed to conduct the study will be released, and
3) The confidentiality of beneficiary information is protected.
5) In addition, we would ensure that our system of records for claims data would permit these usages of the data.

We request comments on the proposed use of the data for research purposes that would help CMS in its efforts to improve knowledge relevant to public health. We also ask for comments on whether we should consider additional regulatory limitations for external researchers beyond our existing data use agreement protocols in order to further guard against the potential misuse of data for non-research purposes, commercial purposes, or to ensure that proprietary plan data or confidential beneficiary data is not released.