

EXECUTIVE SUMMARY

With the advent of Part D, the Medicare program has an important new source of information that the program can use to improve the health of Medicare beneficiaries. Information from prescription claims about the variety of drugs used by individual beneficiaries and about long term usage of those drugs can improve quality of care in significant ways-it can alert beneficiaries and their physicians to potentially harmful interactions; it can identify potentially harmful overuse of medications; and it can inform understanding of beneficiary behavior that results in under-treatment of chronic conditions.

To understand this opportunity and how best to take advantage of it, starting in the spring of 2005, the National Committee for Quality Assurance (NCQA) and the Academy of Managed Care Pharmacy (AMCP) worked with Advanced Pharmacy Concepts (APC) to produce this white paper. The paper recommends clinical quality measurement activities in which all Part D plans, stand alone or as part of Medicare Advantage plans, can engage in the near term, as well as opportunities that are more complex to implement and therefore will take more time. Pharmacy benefit managers currently employ many of these activities on behalf of the commercially insured population. Current Centers for Medicare & Medicaid Services (CMS) requirements do not specify such clinical performance measures.

The recommendations in this paper will benefit from further review and discussion by the variety of stakeholders of Medicare Part D-federal legislative and executive agency officials; Part D plans; health care practitioners and beneficiary representatives. NCQA and AMCP plan to further such discussion. Discussion will include how Part D plans can act most effectively on information they collect and how to construct quality measures that assess the effectiveness of such actions by Part D plans.

The Quality Gap and Opportunities for Improvement

Health care in the United States is provided through a diverse network of private corporations and individual practitioners. These entities do not share a common database of medical information and have a limited ability to efficiently coordinate health care for individual patients.

The lack of a comprehensive systematic assessment of health care quality in the United States also complicates accurate quality assessment and improvement. At present, there are few quality measures that are consistently collected and evaluated, and these measures do not encompass all sectors of the health care industry. In particular, “quality” with regard to pharmacy services is not well defined, and when it is addressed, the oversight measures tend to set narrow targets.

The establishment of a prescription drug benefit for Medicare beneficiaries represents a major opportunity for quality assessment and improvement. Plan sponsors are the only entities possessing all pharmacy claims data for a member — more information than is generally available to individual prescribers or pharmacies. Even prescriptions that the Part D member pays out-of-pocket will be captured when the member uses his/her membership card for the cash discount it affords. Therefore, the Part D plan is given both the opportunity and responsibility for identifying problems and bringing them to the attention of the prescriber, pharmacy or beneficiary.

Immediate Opportunities for Clinical Action and Measurement

CMS can implement requirements for action by Part D plans in phases. CMS has begun with an emphasis on operational functions, particularly related to ensuring access to beneficiary services, medications and accuracy in tracking beneficiary costs. To further realize the potential of Part D to improve beneficiary health, the next phase must include measures of plan actions based on validated research; readily-available pharmacy claims data and commonly utilized drug utilization review processes. These measures should address:

- Identification and reporting of over-utilization including overdosage, toxicity, use without indication and potential misuse or abuse
- Detection and reporting of under-utilization
- Sub-optimal drug therapy
- Adverse event recognition and reporting.

Exhibit 1 outlines potential Part D plan responsibilities related to each type of drug-related problem. In particular, a set of clinical performance measures for Part D plans should include measurement of care related to chronic conditions most prevalent for Medicare beneficiaries (refer to Exhibits 3-5).

While Part D plans can and should be accountable for identifying medication problems and notifying the appropriate entities (i.e., prescriber, pharmacy or beneficiary), the plans do not have control over whether those entities acknowledge the problem or take action to correct it. It will be important for all stakeholders to consider how Part D actions, based on data at their disposal, can be most effective.

Other Opportunities for Clinical Action and Measurement

Many quality measures assess appropriate treatment of a disease using information from both medical and pharmacy claim databases. Health plans access both types of data for quality assessment and improvement activities. Even within a health plan, this can be technologically complex and costly.

Within the current Medicare program, Medicare Advantage (MA-PD) plans have access to medical and pharmacy claim data and use that data for quality improvement and

performance reporting. Medical and pharmacy claims for the remaining beneficiaries in the fee-for-service program are submitted to separate payors, whose datasets are not readily accessible to each other. Stand-alone Part D plans have access only to pharmacy claim data, limiting their ability to determine diagnoses and restricting evaluations that assess the appropriateness of the treatment regimen.

The stand-alone Part D plans' lack of access to medical claim data limits their ability to use pharmacy claim data to maximum advantage. If CMS facilitates the linking of medical and pharmacy claim data, Part D plans could engage in more robust quality improvement and measurement activities. An important first step is for CMS to analyze a national dataset to understand the potential information.

Limitations and Gaps

Fragmentation of the Medicare delivery system and limitations on benefits affect the ability of Part D plans to act and to be measured on those actions. Furthermore it is important to consider how actions by stand-alone Part D plans fit into the larger, fragmented delivery system. Key questions include, how should Part D plans communicate with physicians? What do we expect physicians to do with the information they receive? How can Medicare hold them accountable? How and when should Part D plans communicate with beneficiaries? How should these activities be coordinated with Medicare Health Support Pilot activities, especially if Medicare Health Support expands?

Other limitations involve limitations of the Part D benefit, such as non-covered medications and the coverage gap. These limit some opportunities for data and action based on that data. Certain populations, traditionally underserved population subgroups and long-term care patients, are particularly vulnerable to potentially harmful medication misuse and pose special challenges such as, cultural and language barriers and cognitive impairments. Consideration of these limitations will allow greater realization of the potential of Medicare Part D for all beneficiaries.

Recommendations

Following are key recommendations of the paper:

1. Part D plans can improve the health of Medicare beneficiaries through efforts to identify and act on:
 - Medication overuse
 - Medication underuse
 - Sub-optimal drug therapy
 - Adverse drug events
2. Initial measures should focus on quality improvement activities that can be implemented using pharmacy data exclusively, combined with outreach to pharmacies, patients and providers.

3. Creating a well-developed set of clinical performance measures will focus plan actions and facilitate evaluation and comparison of plans. Current Medicare requirements do not specify such clinical performance measures. Well-developed evidence, processes and a few medication measures currently exist for Part D plans to begin such clinical performance measurement.
4. A clinical set of performance measures for Part D plans should take into account chronic conditions most prevalent among Medicare beneficiaries and include standardized measures related to those conditions. Currently available evidence, processes and medication measures make this possible.
5. In the future, Part D plan measurement and action can be more robust if CMS links medical and pharmacy data and establishes expectations about using the linked data. An initial national dataset can inform stakeholders about the usefulness of this data and technical and cost issues related to creating the data set.
6. A group of multi-stakeholder advisers should consider these recommendations and develop an implementation plan that takes into account the nature of relationships between Part D plans, providers and beneficiaries and builds on best practices for effective use of pharmacy data.

Conclusion

The Part D program will provide prescription drug benefits for up to 43 million Medicare beneficiaries. For the first time Medicare will have responsibility for utilization of medications by beneficiaries. Exercising this responsibility will require standards that make clear how beneficiaries achieve optimal outcomes while minimizing underuse, overuse and adverse events that can lead to higher costs for the health care system, and more importantly, harm or even death, to individuals. It is equally important that oversight and evaluation of Part D plans hold plans accountable for meeting those standards. Currently in use in the commercial sector, well-developed evidence, processes and in specific areas, measures, exist that can be implemented immediately. In the longer term, Part D plan measurement and quality improvement can be even more robust if CMS links pharmacy claim data with medical claim data.