

Developing a Robust  
Quality Measurement  
Approach *for*

Medicare Part D

M A Y 2 0 0 6



*Measuring the Quality of America's Health Care*

This paper was commissioned by NCQA and AMCP and was prepared by Advanced Pharmacy Concepts (APC).

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# EXECUTIVE SUMMARY

**W**ith 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 sub-groups 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.

## 4

### *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.

Since 2004, The National Committee for Quality Assurance (NCQA) and the Academy of Managed Care Pharmacy (AMCP) have collaborated to strengthen the quality assessment components for the Medicare Part D program. NCQA and AMCP met with Centers for Medicare & Medicaid Services (CMS) officials in December 2004 to present ideas for standards and performance measures for a Part D quality assessment program. In the spring of 2005, NCQA and AMCP commissioned Advanced Pharmacy Concepts (APC), a pharmacy benefits consulting firm, to draft a white paper identifying potential clinical performance measures for evaluating Part D plans. The resultant paper follows.

## INTRODUCTION

Medicare beneficiaries now have access to an outpatient prescription drug benefit established by Congress as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).<sup>1</sup> Known as **Medicare Part D**, the benefit is administered through stand-alone prescription drug plans (PDP) and Medicare Advantage prescription drug plans (MA-PD), referred to in this document as **Part D plans**.

In the months and years to come, providers and beneficiaries will begin to understand issues such as eligibility and coordination of benefits, but one aspect of the Part D program will remain of paramount importance: quality assurance. Ensuring quality outpatient prescription drug coverage is vital to achieving the MMA's objective to "advance the goal of improving quality and increas[ing] efficiency in the overall health care system."<sup>2</sup>

Health care quality improvement is an important objective of the MMA. Over the past decade, research reports have identified a myriad of shortcomings within the health care industry related to pharmaceutical use. In a landmark study by Johnson and Bootman, the authors developed a theoretical model that estimated that as many as 28 percent of all hospital admissions are the result of drug-related mortality and morbidity.<sup>3</sup> Other health care utilization attributed to medication misuse by their model included emergency room visits, long-term care admissions and physician visits. Additionally, the Johnson and Bootman model estimated that appropriate pharmaceutical care could prevent almost 5 million hospital admissions and more than 100,000 deaths annually. Appropriate care could also reduce the annual cost of drug-related morbidity and mortality from \$76 billion to \$31 billion.<sup>4</sup>

The 1999 Institute of Medicine (IOM) report *To Err Is Human: Building a Safer Health System* identified serious patient safety problems in inpatient health care organizations. The report estimated that 44,000 to 98,000 Americans die each year from medical errors, and hundreds of thousands more suffer nonfatal injuries.<sup>5</sup>

This document addresses a variety of issues associated with the development of a set of validated quality measures for Part D plans, and proposes measures to focus the activities of Part D plans and support plan evaluation and comparison.

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The second IOM report, *Crossing the Quality Chasm: A New Health System for the 21st Century*, identified widespread health care deficiencies and proposed an agenda for sweeping improvements throughout the entire health care system.<sup>6</sup> Medication-related care is no exception. Up to 7,000 deaths each year are related to inpatient medication errors, and the estimated annual cost of drug-related morbidity is almost \$77 billion.<sup>7</sup> Only about 70 percent of adults with chronic conditions receive recommended medications.<sup>8</sup>

This document addresses a variety of issues associated with the development of a set of validated quality measures for Part D plans, and proposes measures to focus the activities of Part D plans and support plan evaluation and comparison. The measures focus on clinical quality activities to complement existing assessments of financial accuracy, customer-service quality and utilization patterns.<sup>9</sup>

This paper recommends clinical quality measurement activities in which all Part D plans can engage in the near term singly or as part of MA plans, as well as opportunities that are more complex to implement and will therefore take more time. Pharmacy benefit managers currently employ many of these activities on behalf of the commercially insured population; this paper recommends that existing proven, effective processes and activities be implemented in the Medicare Part D program.

## A. Health Care Quality Assessment

**Quality assessment** is the first step in the process of quality improvement. Examining the difference between the top percentile and the national average of all performers within a business sector is a standard quality assessment tool. In other business sectors, such as the airline industry, banking or manufacturing, the difference between the top percentile of performers and the national average is often nominal; for example, less than 1 percent for the airline industry. But the difference between the top 10 percent of health plans and the national average—termed the “quality gap”—was as high as 20 percent on certain measures in 2004.<sup>10</sup> In general, as plans have continued to measure, the gap has narrowed.

*Why is the quality gap in health care so large?* Within the United States, inconsistencies in health care quality stem from several variables. Health care is provided through a diverse network of private corporations and individual practitioners that do not share

a common database of medical information and have a limited ability to efficiently coordinate health care for individual patients. Often, the primary source of information about a patient is obtained through patient self-reporting, which can be inconsistent or incomplete.

Socioeconomic and geographic considerations impact the ability of individuals to access care. A significant portion of the U.S. population does not have health insurance coverage because the cost is prohibitive. Many health care services may not be offered in rural or inner city locations, limiting the ability of people living in these locations to access care.

The lack of an established process for comprehensive, systematic assessment of health care quality also complicates accurate quality assessment and improvement.<sup>11</sup> At present, there are relatively few quality measures that are consistently collected and evaluated, and these 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 be narrowly drawn.

The need for a validated, standardized assessment of the quality of outpatient drug benefits did not begin with the establishment of Medicare Part D. Early pharmacy quality concerns were highlighted as many states shifted patients from traditional Medicaid programs into Medicaid managed care, where the use of pharmacy benefit managers (PBM) was common for pharmacy programs. Concern about these programs was sparked by mergers and alliances between pharmaceutical manufacturers and PBMs. In 1993-1994, PBM services were investigated by the Food and Drug Administration (FDA), Federal Trade Commission (FTC) and the General Accounting Office.<sup>12</sup> In 1997, the Office of the Inspector General recommended that the Health Care Financing Administration (HCFA), now the Centers for Medicare & Medicaid Services (CMS), support the development of measures to assess the quality of pharmacy services delivered to beneficiaries by health maintenance organizations (HMO).<sup>13</sup>

Although the MMA contains over 70 references to health care quality, it does not define quality in relation to Medicare Part D. For example, section 1860-D-4(c) states: “the PDP sponsor shall have in place either directly or through appropriate arrangements [...] quality assurance measures and systems to reduce medication errors and adverse drug reactions and improve medication usage.” A degree of flexibility has been given to plans to design quality assurance measures as long as minimum standards (as defined by CMS) are met.<sup>14</sup> Although flexibility was reasonable, given uncertainties in plan sponsor participation, there should be structured quality measures and basic minimum standards to which plans are held.

The literature demonstrates that measurement leads to improvement in all industries, and health care is no exception. For example, health plans accredited by NCQA have made significant improvements in important quality indicators such as hypertension,

There is a need to develop quality measures that assess outpatient drug benefits within their own primary context; to recognize the interaction between stand-alone plans and other segments of the health care industry; and to identify Part D plan responsibilities.

diabetes care, hyperlipidemia and asthma control.<sup>15</sup> These improvements translate into reduced mortality, morbidity and costs, and increased quality of life for millions of people.

The Part D program will provide prescription drug benefits for up to 43 million Medicare beneficiaries. For the first time, Medicare will be responsible for how its beneficiaries utilize medications. Exercising this responsibility will require standards that clearly state how beneficiaries can 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 beneficiaries. It is equally important that oversight and evaluation of Part D plans holds the plans accountable for meeting those standards.

Within the past decade, provider performance assessment has become accepted practice within the health care industry and many resources are available regarding quality assessment (refer to Appendix 1 for examples). As indicated above, few existing measures were designed specifically to assess outpatient drug plans such as those established by Part D. There is a need to develop quality measures that assess outpatient drug benefits within their own primary context; to recognize the interaction between stand-alone plans and other segments of the health care industry; and to identify Part D plan responsibilities. In doing so, it is important to keep in mind that stand-alone Part D plans act independently within Medicare and, in many cases, do not have formal relationships with providers or access to medical claims from other providers of beneficiary care. Part D plans will, however, possess comprehensive, coordinated prescription drug claim data that they can use to achieve the MMA's objective of advancing and improving quality and efficiency in the industry.

## B. Principles for Quality Measures

**Quality measurement** is key to promoting accountability for quality improvement activities. Quality measurement requires resources, and those imposing requirements for quality measurement must ensure that resources are used for meaningful activities. Performance measures must meet scientific and feasibility criteria.

The majority of plans participating in Part D offer stand-alone pharmacy benefits and do not have ready access to necessary clinical information often required for measuring quality, including diagnosis, laboratory or radiological findings and information on use of other health care resources. Consequently, clinical quality measures should rely on information available in the pharmacy claims dataset, at least for the first few years following implementation.

This paper proposes principles for measure development adopted by the National Quality Forum (NQF), which are virtually identical to those used by NCQA for HEDIS® measure development and are importance, scientific acceptability, feasibility and usability.<sup>16</sup>

### *Importance*

This addresses the extent to which a measure reflects variation in quality and low levels of overall performance and how it captures key aspects of the flow of care:

- The measure addresses one or more key leverage points for improving quality.
- There is considerable variation in the quality of care.
- Quality performance (e.g., setting, procedure, condition) is suboptimal, suggesting that barriers to improvement or best practice may exist.

### *Scientifically Acceptable*

A measure is scientifically sound if it produces consistent and credible results when implemented.

- The measure is well defined and precisely specified so that it can be distinguished from other measures. It has been implemented consistently across institutions and its specifications provide details about cohort definition, as well as the denominator and numerator for rate-based measures and categories for range-based measures.
- The measure is reliable, producing the same results a percentage of the time when assessed in the same population.
- The measure is valid, accurately representing the concept being evaluated.
- The measure is precise, adequately discriminating between real differences in provider performance.
- The measure is adaptable to patient preference and a variety of settings. Adaptability depends on the extent to which the measure and its specifications account for the variety of patient choice, including refusal of treatment and clinical exceptions.
- An adequate and specified risk-adjustment strategy exist, where applicable.
- Consistent evidence linking process measures to patient outcome is available.

### *Useable*

Usability reflects the extent to which intended audiences (e.g., consumers, purchasers) can understand the measure's results and are likely to find them useful for decision making.

- The measure can be used by the stakeholder to make decisions.
- The differences in performance levels are statistically meaningful.
- The differences in performance are practically and clinically meaningful.
- Risk stratification, risk adjustment and other forms of recommended analyses have been applied appropriately.
- Effective presentation and dissemination strategies exist (e.g., transparency, ability to draw conclusions, information available for decision making).

- Information produced by the measure can or will be used by at least one healthcare stakeholder audience (e.g., public/consumers, purchasers, clinicians and providers, policymakers, accreditors/regulators) to make a decision or take an action.
- Information about specific conditions for which the measure is appropriate has been given.
- Methods for aggregating the measure with other, related measures (e.g., to create a composite measure) have been defined if related measures have been determined to be more understandable and more useful in decision making. Risks of such aggregation, including misrepresentation, have been evaluated.

### *Feasible*

Feasibility is generally based on how data can be obtained within the normal flow of clinical care and the extent to which an implementation plan can be achieved.

- The point of data collection is tied to care delivery, when feasible.
- The timing and frequency of measure collection are specified.
- The benefit of measurement has been evaluated against the financial and administrative burden of implementation and maintenance of the measure set.
- An auditing strategy was designed and can be implemented.
- Confidentiality concerns have been addressed.

## C. Report Format

This document is divided into five sections that provide background for quality measures in pharmacy benefits; address the ability of Part D plans to address drug-related problems in the short and long term; discuss quality measures for chronic conditions specific to the Medicare population; and discuss barriers to implementing quality monitoring and measurement.

**Section I: Plan Sponsor Responsibilities** outlines current statutory requirements and clinical issues within the sphere of Part D plan accountability.

**Section II: Existing Quality Improvement Tools** discusses processes currently available to improve the quality of medication use, including drug utilization review and medication therapy management.

**Section III: Quality Assessment-Short-Term Objectives** identifies measurement opportunities for assessing the quality of pharmacy benefit administration in the near future. The measures discussed in this section are based on readily available pharmacy claim data and address, overutilization, underutilization and adverse event prevention and recognition.

**Section IV: Care of Chronic Conditions** identifies disease-specific measures, addressing chronic conditions prevalent within the Medicare population. This section discusses how measures specific to prevalent disease states can be incorporated into requirements for Part D programs.

**Section V: Long-Term Quality Assessment** focuses on key activities and performance measures of activities that will require additional data or further research for implementation.

**Section VI: Barriers to Implementation of Quality Measurement** details barriers to quality improvement and assessment. Particular areas of concern include the impact of non-covered medications and the lack of accurate diagnosis information and provider identification.

**Section VII: Quality Lapses in the Part D Program** discusses potential quality lapses inherent within the Part D benefit and addresses the impact of these lapses on the population as a whole, as well as on traditionally underserved population subgroups and long-term-care patients.

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# SECTION I:

## Part D Plan Responsibilities

### A. Operational Expectations

Current CMS requirements focus on operational functions for Part D plans, particularly with regard to ensuring access to appropriate medications and accuracy in tracking beneficiary costs. These requirements may also affect certain clinical areas and their impact must be considered during quality measure development and implementation.<sup>17</sup> In certain instances, operational or process measures may, in fact, have a direct impact on clinical quality areas. Operational expectations include, but are not limited to:

- Accuracy of eligibility and enrollment.
- Accuracy of claims adjudication and the integrity of any subsequent data provided to CMS.
- Accuracy of benefit design set-up and implementation.
- Accurate calculation, application, accumulation and reporting of member cost shares.
- Accurate calculation, accumulation and reporting of True Out Of Pocket (TrOOP) expenditures.
- Accurate and timely coordination of benefits.
- Appropriate and timely administration of prior authorization and medical exception process.
- Appropriate compliance with call center administration and service metrics.
- Compliance with standards of appropriate marketing materials and activities.
- Ensuring accuracy and integrity of financial data.
- Ensuring sufficient pharmacy access to members.
- Ensuring appropriate and timely access to a grievance process.
- Ensuring formulary access and compliance with requirements.
- Oversight of Pharmacy and Therapeutics (P&T) Committee decisions to ensure compliance with requirements.
- Provision of enrollee education communications regarding fraud, waste and abuse.
- Timely and appropriate resolution of member complaints.

Plans will also soon be submitting both encounter level data, known as Prescription Drug Event data, and additional quarterly reports that include data elements related to:

- Enrollment and disenrollment.
- Claim reversals.
- Medication therapy management program.
- Grievances.
- Prior authorization, step edits, nonformulary exceptions and tier exclusions.
- Appeals.
- Call center measures.

- Overpayment.
- Pharmaceutical manufacturer rebates, discounts and other price concessions.
- Licensure and solvency, business transactions and financial requirements.

Reporting requirements implemented by CMS include some clinical measures (refer to Appendix II). **Generic dispensing rate** — the ratio of paid claims for generic products to the total number of paid claims — will be calculated and reported quarterly.<sup>18</sup>

Maximizing generic utilization reduces medication costs for plans and members, and does not adversely affect outcome of care.

Plans are required to report quarterly metrics related to drug-utilization management and appropriate formulary design, including:

- Number of claims rejected for failure to meet step-therapy requirement or need for prior authorization.
- Number of prior authorizations requested and approved for formulary and non-formulary medications.
- Number of tier exceptions requested and approved.<sup>19</sup>

While CMS has not established explicit requirements for the design of Medication Therapy Management (MTM) programs for Part D plans, CMS requires that several data elements related to the MTM program be reported semiannually.<sup>20</sup> These elements include:

- The number of beneficiaries who met the criteria for the MTM program during each six-month reporting period.
- The number of beneficiaries who participated in the MTM program at any time during each six-month reporting period.
- The number of beneficiaries who declined the offer to participate in the MTM program during each six-month reporting period.
- Total ingredient cost of all medication claims for beneficiaries participating in the MTM program, reported per participating beneficiary per month of eligibility within the six-month reporting period.

CMS will use plan-submitted data to develop reports and related intervention metrics to monitor quality, safety, regulatory and payment compliance.<sup>21</sup>

As stated in the final rules and regulations for the MMA, evaluation of these programs and systems must be based on their impact on therapeutic outcomes.<sup>22</sup> Specific areas of analysis include calculation of medication adherence and persistence, identification of drug-drug interactions and drug safety issues.<sup>23</sup>

Due to their unique level of access to pharmacy claims adjudication data, Part D plans are the only entities that can take responsibility for identifying opportunities for comprehensive medication management activities. Identification and response to drug-related

Plans should focus and be measured on their ability to take appropriate actions to prevent or mitigate problems, recognizing that they have limited influence over actual prescribing or patient adherence.

problems are congruent with the operational functions of plans in administering the Part D benefit. A comprehensive quality program will include measures that address each area of a plan's clinical responsibility. Plans should focus and be measured on their ability to take appropriate actions to prevent or mitigate problems, recognizing that they have limited influence over actual prescribing or patient adherence. These responsibilities are summarized in Exhibit 1, and quality measures related to each area are presented in sections III, IV and V of this document.

## B. Clinical Responsibilities

It is not uncommon for different types of providers, including prescribers and pharmacies, to administer the same or duplicate therapies for a patient without realizing it. Only Part D plans possess data on patients' entire prescription history—more information than is generally available to individual providers or pharmacies, who would be aware only of what they prescribe or dispense to a patient. Even prescriptions paid out of pocket are captured when Part D members use their benefit card; therefore, a plan sponsor has the opportunity and responsibility for identifying problems and bringing them to the attention of the provider or pharmacy.

Accountability is key. What is the responsibility of Part D plans, particularly stand-alone plans, that have no formal relationship with other parts of the delivery and insurance system? This paper's short-term measure recommendations build on Part D plans' access to key data, and propose areas for quality assessment and measurement that make use of these data. CMS and others can use these measures to evaluate contributions of Part D plans toward enhancing quality care for Medicare beneficiaries. It is important to build on existing best practices so that the plans implement meaningful, effective processes and activities to identify and communicate potential drug-related problems to prescribers and beneficiaries.

Part D plans can play an important role in comprehensive medication management activities, by monitoring and notifying the appropriate parties (i.e., prescribers, patients, CMS) of potential and actual medication problems, including:

- Identifying and reporting overutilization, including overdose, toxicity, use without indication and potential misuse or abuse.
- Detecting suboptimal therapy for acute and chronic conditions.
- Detecting and reporting underutilization, including poor adherence, failure to receive treatment, untreated indications and use of subtherapeutic doses.
- Recognizing and reporting adverse events.

Exhibit 1 provides examples. Long term opportunities would require medical claim data.

Working with a multi-stakeholder advisory group, CMS can sponsor development of, and require Part D plans to report, a set of standardized performance measures of Part D plan actions in the above areas. These measures will clarify expectations for

Part D plans; provide a means of evaluating plans against expectations and, ultimately, provide a method of comparing plan performance.

**RECOMMENDATION:**

- *Part D plans can improve beneficiary health through efforts to identify and act on medication over- and underuse, suboptimal drug therapy and adverse drug events.*
- *Initial measures should focus on quality improvement activities that can be implemented using pharmacy data exclusively, combined with outreach to pharmacies, patients and providers.*

Exhibit 1: Drug-Related Problems and Associated Plan Responsibilities

| Drug-Related Problem <sup>a</sup> | Role of the Part D Plan  |
|-----------------------------------|--|
| <b>Suboptimal Medication Use</b>  |  |
| Appropriate drug selection        | <p><b>Short-term:</b> Identify and report optimal drug therapy selection for diseases that can be inferred from pharmacy claims, such as diabetes, asthma and HIV.</p> <p><b>Long Term:</b> Identify the impact of suboptimal therapy on other health care utilization, including hospital admissions and emergency care.</p>  |
| Optimal duration of therapy       | <p><b>Short-term:</b> Identify and report optimal drug therapy duration for diseases that can be inferred from pharmacy claims, such as depression.</p> <p><b>Long Term:</b> Identify the impact of suboptimal therapy duration on other health care utilization, including hospital admissions and emergency care.</p>  |
| <b>Medication Overuse</b>         |  |
| Use without indication            | <p><b>Short-term:</b> Limited ability to measure using pharmacy claim information alone; however, use without indication may be identified and targeted for intervention through the MTM program.</p> <p><b>Long-term:</b> Identify potentially unnecessary medication utilization through integration of pharmacy and medical claim data.</p>   |
| Overdose/toxicity                 | <p><b>Short-term:</b> Evaluate and report the impact of DUR alerts, such as high dose, overuse, early refill, excessive duration, therapeutic duplication, ingredient duplication, potential abuse and additive toxicity on patient utilization and potential fraud; implement corrective actions and improvements in DUR alert effectiveness based on findings.</p> <p><b>Long-term:</b> Identify and prevent medical claims related to medication toxicity, and ensuring appropriate laboratory monitoring of high-risk medications.</p> |
| Improper drug selection           | <p><b>Short-term:</b> Identify and report the frequency of use of potentially-inappropriate medications among the elderly and other Medicare populations.</p> <p><b>Long-term:</b> Utilize medical claim data to prevent drug-disease contraindications and promotion of appropriate medication selection for the applicable disease state.</p>  |

| Drug-Related Problem <sup>a</sup> | Role of the Part D Plan   |
|-----------------------------------|---|
| <b>Medication Underuse</b>        |   |
| Untreated indication              | <p><b>Short-term:</b> Limited ability to measure through claim information. However, untreated indications may be identified and targeted for intervention through the MTM program.</p> <p><b>Long-term:</b> Identify untreated indications through medical claim data and promotion of appropriate treatment according to nationally-recognized practice standards.</p>  |
| Subtherapeutic dosage             | <p><b>Short-term:</b> Identify and report the prevalence of subtherapeutic dosage based on DUR edits, including low-dose alerts, underuse precautions and insufficient duration alerts. The plan should attempt to reduce the frequency of subtherapeutic dosage, bearing in mind the special needs of the Medicare population.</p> <p><b>Long-term:</b> Availability of medical claim data may allow patient-specific dose evaluations, based on laboratory results or other therapy outcomes.</p> |
| Failure to receive medication     | <p><b>Short-term:</b> Identify and report instances in which patients fail to receive medication, using claim reversal records and MTM findings as a basis for initiating assessments. Identify and improve persistence and adherence and reduce identified barriers to claim fulfillment.</p> <p><b>Long-term:</b> Will most likely be similar to quality measures used to assess failure to receive medication in the short term.</p>   |
| <b>Adverse Drug Events (ADE)</b>  |   |
| Adverse drug reactions            | <p><b>Short-term:</b> Identify the prevalence of adverse drug reactions within and across drug classes, drug dose and patient populations, based on reactions that can be inferred from pharmacy claim data.</p> <p><b>Long-term:</b> Identify and prevent inappropriate medication-use-induced health care utilization (including hospital admissions) and claims for treatment of known adverse effects.</p>  |
| Drug interactions                 | <p><b>Short-term:</b> Measure the effectiveness and impact of DUR alerts, including drug-drug interactions and drug incompatibilities (see Section I A).</p> <p><b>Long-term:</b> Will likely be similar to the DUR alerts used in the short-term.</p>  |

<sup>a</sup> Drug-related problems as defined in Strand, L.M., P.C. Morley, R.J. Cipolle, et al. Drug-related problems: Their structure and function. DICP 1990; 24: 1093-1097.

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## SECTION II: Existing Quality Improvement Tools

Within a health care organization, quality assessment identifies areas of underperformance that may adversely affect patient care; they have become standard for many sectors of the health care industry. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) assesses patient safety and quality of care within inpatient health care facilities. The HEDIS® set of performance measures assesses health plan quality and NCQA evaluates and publicly reports results as part of NCQA Accreditation of managed care organizations (MCO). Medicare Quality Improvement Organizations (QIO) assess quality in physician offices, home health organizations, hospitals and nursing homes.

Despite well-established quality assessment programs in other areas of health care, to date there are no standard performance measures for assessment of stand-alone prescription drug plans such as those offered by pharmacy benefit managers (PBM) to commercial clients and the Medicare Part D PDPs. Medication management and safety are components of other quality evaluations, including JCAHO and NCQA programs that MA-PDs may be tracking and reporting. While these assessments are useful to measure quality within a health care organization, they are insufficient for Part D plans, for a variety of reasons. To adequately assess and improve quality within the Medicare Part D program, a set of quality measures specific to the needs and goals of these plans must be validated and implemented in the near term.

To set the stage for a proposed quality program, it is necessary to understand the processes currently employed by health plans and PBMs: drug utilization review and medication therapy management. These processes are required for plans participating in Part D. It must be noted that while CMS requires plans to have utilization management, quality assurance and medication therapy management activities, it has not specified the exact processes or tools that must be used.

This paper proposes a framework for developing specific actions, processes and measures within the scope of CMS requirements that plans can take to improve clinical outcomes.

Despite well-established quality assessment programs in other areas of health care, to date there are no standard performance measures for assessment of stand-alone prescription drug plans such as those offered by... Medicare Part D PDPs... To adequately assess and improve quality within the Medicare Part D program, a set of quality measures specific to the needs and goals of these plans must be validated and implemented in the near term.

## A. Drug Utilization Review

**Drug utilization management** is the process of managing the use of pharmaceutical resources to ensure that a patient receives necessary, appropriate, high-quality care in a cost-effective manner.<sup>24</sup> Concurrent and retrospective drug utilization review programs help manage cost, provide quality assurance and prevent fraud. Prospective DUR or evaluating a patient's medication regimen prior to dispensing will have limited applicability for stand-alone Part D plans — it requires plan involvement *before* the prescription reaches the pharmacy. This does not occur with Part D plans currently, but should increase with the use of electronic prescribing. Formulary design characteristics can also influence drug utilization.

### 1. Concurrent Drug Utilization Review

Concurrent drug utilization review (cDUR) functions are provided at the point of service (POS) and include real-time system edits that can affect prescribing patterns. In state Medicaid programs, these types of edits have been in place since the adoption of the Omnibus Budget Reconciliation Act (OBRA) of 1990. The same tools are features of drug utilization management programs administered by private PBMs. Standard cDUR alerts are listed in Exhibit 2.

A thoughtfully designed DUR alert system, integrated into a targeted patient care improvement program, is an effective tool for improving the quality of drug utilization for Medicare recipients. Providers are inundated with information that is overlooked or ignored—the key is to design alerts so that they are recognized and acted on in a timely fashion.

### 2. Retrospective Drug Utilization Review

Retrospective drug utilization programs (rDUR) are common in both commercial and state Medicaid programs, as well as in long-term care settings. Retrospective drug review has inherent limitations because it is conducted after the first prescription has been filled. Recognizing this, administrators have expanded follow-up activities to increase the effectiveness of these programs. Some enhancements are telephone follow-up with providers; issuing actionable and precisely written letters to prescribers; and academic detailing programs. Drug utilization management efforts overall are enhanced by using rDUR findings to systematically and regularly update cDUR edits.

Drug utilization review, computerized or conducted by individual practitioners, can improve suboptimal medication use among elderly patients. Pharmacist intervention via physician contact, prompted by a computerized alert, resulted in a significant rate of medication change at mail-service pharmacy facilities. Specifically, drug-age interventions (drugs known to be harmful in the elderly), supratherapeutic dose interventions and disease-specific interventions resulted in 24 percent, 25 percent and 5 percent rates of change, respectively.<sup>25</sup>

Exhibit 2: DUR Alerts<sup>a</sup>

| Drug-Related Problem             | Related DUR Alert   |
|----------------------------------|---|
| <b>Medication Overuse</b>        |   |
| Drug use without indication      | None  |
| Overdose/toxicity                | <ul style="list-style-type: none"> <li>• High dose alert</li> <li>• Overuse precaution</li> <li>• Excessive duration alert</li> <li>• Therapeutic duplication</li> <li>• Ingredient duplication</li> <li>• Additive toxicity</li> </ul> |
| Improper drug selection          | <ul style="list-style-type: none"> <li>• Drug-disease precaution</li> <li>• Drug-age precaution</li> <li>• Drug-pregnancy alert</li> <li>• Drug-sex alert</li> </ul>  |
| <b>Medication Underuse</b>       |   |
| Untreated indication             | None  |
| Subtherapeutic dosage            | <ul style="list-style-type: none"> <li>• Low dose alert</li> <li>• Underuse precaution</li> <li>• Insufficient duration alert</li> </ul>  |
| Failure to receive drug          | None  |
| <b>Adverse Drug Events (ADE)</b> |   |
| Adverse drug reaction            | <ul style="list-style-type: none"> <li>• Side effect alert</li> <li>• Prior adverse drug reaction</li> <li>• Drug allergy alert</li> </ul>  |
| Drug interaction                 | <ul style="list-style-type: none"> <li>• Drug-drug interaction</li> <li>• Drug-food interaction</li> <li>• Drug incompatibility</li> <li>• Drug-laboratory conflict</li> </ul>  |

<sup>a</sup> *J Am Pharm Assoc.* 2002; 42:444

rDUR can be used to determine drug use patterns within a population and implement changes to the pharmacy benefit program to improve the quality of drug use and deter fraud. Such retrospective claim review may allow a Part D plan to develop reviews at an individual beneficiary level to identify instances in which combinations of therapy result in daily doses of an ingredient exceeding the maximum recommended dose.

## B. Medication Therapy Management

Medication therapy management (MTM) is a distinct service or group of services that optimize therapeutic outcomes for individual patients by helping them to appropriately utilize all their prescribed medications. MTM focuses on individual patients, with the goal of maximizing the benefits of medication therapy while minimizing the risk of adverse events.

Well-developed MTM programs can improve health care quality and reduce annual expenditures for patients with chronic diseases. Published information describes MTM programs that have been implemented by pharmacists in collaboration with other health providers and in various practice settings. Examples of such programs in outpatient settings include those for hypertension treatment,<sup>26, 27</sup> hyperlipidemia therapy,<sup>28</sup>

anticoagulation therapy,<sup>29, 30</sup> and tuberculosis management.<sup>31</sup>

An in-depth review of existing MTM services and the evidence supporting improved outcomes is available from the American Pharmacists' Association.<sup>32</sup>

The Medicare Modernization Act (MMA) mandates that Part D plans implement MTM programs. This requirement represents an opportunity for plans to evaluate and improve medication utilization among a subset of members with multiple chronic

conditions. While a plan can include additional members in its MTM program, members with multiple chronic conditions who take multiple medications and are likely to incur high drug costs must be given the opportunity to enroll. 23 percent of Medicare beneficiaries have 5 or more chronic conditions, making a majority of them eligible to meet at least 1 of the 3 criteria required for inclusion in the MTM program. These beneficiaries fill an average of 20 prescriptions per year, account for 68 percent of Medicare spending and will likely account for a significant proportion of a plan's annual expenditures.<sup>33</sup> Based on CMS requirements, measures will need to assess the quality and robustness of MTM programs. AMCP has developed a consensus framework for sound MTM programs that could serve as the basis for developing MTM measures for Part D plans.<sup>34</sup>

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Well-developed MTM programs can improve health care quality and reduce annual expenditures for patients with chronic diseases.

## SECTION III: Quality Assessment — Short-Term Objectives

Quality assessment for the first few years following Medicare Part D implementation will most likely rely on existing quality tools, such as drug utilization review and medication therapy management, and will be limited to measures that can be generated using readily available pharmacy claim data. Since Medicare Part D is a new benefit, plans will have little or no claims history on their members and therefore will not be able to longitudinally evaluate member quality of care until the program is more mature.

This section addresses quality objectives that can be implemented with little claims history and applied immediately. The sections below follow the descriptions of drug-related problems identified in Exhibit 1.

### A. Medication Overuse

#### 1. *Use Without Indication*

Without ready access to medical claim data or formal relationships with other parts of the health care delivery and insurance systems, Part D plans must either contact members or providers directly to obtain diagnostic information or speculate based on medication utilization, a process further complicated by medication use without indication. Without medical claim data, stand-alone Part D plans cannot identify incidents of potential overuse.

It is possible that over time, CMS could include diagnostic information derived from existing Medicare Part A and Part B databases with eligibility information supplied to Part D plans. Using Medicare-generated diagnostic fields, Part D plans could cross-reference drug utilization trends against diagnoses to identify therapy without appropriate indication. But the diagnostic information contained in the Medicare Part A and Part B databases may not be comprehensive: many health care providers are hesitant to code certain diagnoses, such as HIV or mental health conditions, out of patient-confidentiality concerns. Additionally, medical claim forms are limited in the number of diagnoses that can be submitted with each claim; thus, some diagnoses may be omitted on claims for patients with multiple conditions.

#### 2. *Overdose/Toxicity*

Certain population subgroups, including elderly patients, are especially vulnerable to ADEs related to inappropriate dosage. Exceedingly high doses or (less commonly) low doses are associated with a greater risk of adverse events and treatment failure.

Part D plans may play a role in assuring members' use of appropriate medication dose. Performance measures to assess appropriate medication dose include:

- \* Frequency of use of a sedative-hypnotic medication for an excessive time period.
- \* Rate of medication doses above the maximum recommended dose per 1,000 claims.
- \* Rate of subtherapeutic medication doses (after the first 90 days of therapy, to allow for dose titration) per 1,000 claims.

An example of a potentially valuable quality monitor pertaining to toxicity can be demonstrated with the drug acetaminophen. Acetaminophen toxicity is the most common cause of acute liver failure in the United States.<sup>35</sup> Attempts by plans to reduce the frequency of acetaminophen overuse may prevent cases of acute liver toxicity among beneficiaries. As many as half of these cases result from the use of prescription and non-prescription acetaminophen-containing products, often for pain or constitutional symptoms.<sup>36</sup>

Single-product acetaminophen dosage limits are standard within the pharmacy benefit industry, but few plans evaluate total acetaminophen dose across a patient's prescription claim history. Plans can easily assess acetaminophen-containing product utilization prospectively and retrospectively and measure the frequency of acetaminophen total daily dose exceeding four grams through monotherapy or combination therapy.

### ***3. Improper Drug Selection***

#### *Potentially-Inappropriate Medications*

Potentially inappropriate medication (PIM) use is common among elderly patients. Nearly 3 percent of elderly patients receive at least one medication that should always be avoided in this population<sup>37</sup> and almost 25 percent of Medicare managed care patients use at least one potentially inappropriate medication. This subset of patients incurs substantially more inpatient and outpatient facility visits and higher costs than members not using a PIM.<sup>38</sup> Estimates of the frequency of PIM use are as high as 40 percent in adults 60 years of age or older.<sup>39</sup> Potentially inappropriate psychotropic medications are prescribed to ambulatory elderly patients at 8.7 percent of office visits.<sup>40</sup>

The Beers criteria combined literature review and expert consensus to develop a list of medications that are potentially inappropriate for use in elderly patients. Two lists of potentially inappropriate medications are presented in the most recent (2003) Beers criteria update.<sup>41</sup> An additional compilation of potentially inappropriate medications was created by Zhan et al in 2001.<sup>42</sup> This list recognizes that some potentially inappropriate medications are necessary in certain clinical situations; hence, the Zhan list is more narrow than the list by Beers, et al.

NCQA recently developed a new HEDIS measure, *Drugs to Be Avoided in the Elderly*, which MA plans will begin reporting this year. A version of this measure is appropriate

for stand-alone Part D plans, as well. Medications that should be avoided in all elderly patients, and are common to all three criteria, include:

- barbiturates
- belladonna alkaloids
- chlorpropamide
- dicyclomine
- flurazepam
- hyoscyamine
- meperidine
- meprobamate
- pentazocine
- propantheline
- trimethobenzamide

Quality measures to assess the use of PIMs include:

- Number of PIM claims, reported as an average number of PIM claims per 1,000 members.
- Number of members who received one PIM or more than one PIM during the reporting period, reported as a percentage of overall membership.
- Change in the number of PIM claims and members with a PIM claim since the previous reporting period.

Part D plans may use various tools to prospectively restrict utilization, including point-of-sale messaging, prior authorization or formulary restriction. Retrospectively, plans may contact members or providers to suggest alternative formulary medications. Quality measures to assess PIM use may include the prevalence of claims for therapeutically inferior products. For example, short-acting, non-dihydropyridine calcium channel blockers, including nifedipine and diltiazem, are associated with an increased incidence of adverse effects and significant variability in blood-pressure control.

The availability of generic, long-acting formulations limits the therapeutic usefulness of short-acting products for patients who cannot tolerate the long-acting dosage forms, most likely due to an inability to swallow intact oral capsules or tablets.

Measures to assess the prevalence of immediate-release nifedipine and diltiazem products among Medicare beneficiaries are an important safety gauge. Part D plans could also notify the appropriate providers (and possibly the beneficiary) of more effective formulations. Such actions may reduce the incidence of adverse events related to these medications.

Plans will be unable to capture claims for several of the medications or medication classes listed as potentially inappropriate for elderly adults. Certain classes of medications that are included in the Beers criteria are excluded from Part D coverage, including nonprescription medications, anorexic agents, medications used for the symptomatic relief of cough and colds, vitamin products, barbiturates and benzodiazepines;<sup>43</sup> therefore, use of the Beers criteria to evaluate medication use among elderly plan participants would be limited to the subset of medications covered by the Part D plan. A comprehensive list of potentially inappropriate medications and their Part D coverage status is available in Appendix III.

...almost 25 percent of Medicare managed care patients use at least one potentially inappropriate medication. This subset of patients incurs substantially more inpatient and outpatient facility visits and higher costs than members not using a PIM.

## B. Medication Underuse

### 1. *Untreated Indications*

Untreated indications may be identified and targeted for intervention through a variety of methods, including a member health status survey and a medication therapy management program. Causes of untreated indication are often difficult to identify. Patients may have experienced an adverse effect from a prescribed treatment and chose to discontinue it rather than seek an alternative medication. Patients or providers may not fully understand the long-term health risk of a condition and may not recognize the benefits of long-term treatment. Patients may choose to decline or avoid care, even with knowledge of the health risk.

Understanding the reasons for untreated indication provides plans and health providers with opportunities to increase the incidence of treatment, when indicated. Quality assessment activities and measures can, and should, focus on initiating treatment for patients who are diagnosed with a chronic condition and are not receiving optimal treatment for the condition, to the degree that the condition can be identified by pharmacy claim data.

### 2. *Subtherapeutic Dosage*

Problems related to a subtherapeutic dose of a medication can occur when medication is prescribed at a low dose or for an insufficient duration of therapy. In either circumstance, the effect on the patient can be detrimental. Subtherapeutic dosing represents inefficient patient care because of the (often significant) expense incurred for minimal benefit.

Part D plans are in an excellent position to measure medication dosage and the inter-related issues of adherence and persistence, and to provide feedback to prescribers and pharmacists regarding patient adherence with therapy. The prescribing physician is

often unaware of the presence of nonadherence. Measurement of drug adherence, based on prescription refill rates and days of therapy indicators, could identify patients who receive suboptimal therapy. If communicated in an effective manner, this information could provide a substantial benefit to the patient and prescriber.

### 3. *Failure to Receive Medication*

In the first few years following Part D implementation, measures related to failure to receive medication will likely focus on measurement of adherence and persistence. **Adherence** (also known as **compliance**) is accurate and consistent use of a treatment, usually a chronic medication. **Persistence** is the continued use of a

Part D plans are in an excellent position to measure medication dosage and the interrelated issues of adherence and persistence, and to provide feedback to prescribers and pharmacists regarding patient adherence with therapy.

medication for a defined treatment period (or indefinitely, for certain chronic conditions). Medication adherence and persistence are influenced by a variety of factors, including cost, regimen complexity and adverse effects; and affect multiple facets of treatment in terms of direction and outcome.

Adherence and persistence are essential to successful therapeutic regimens, especially in chronic conditions. Poor adherence and persistence result in a virtually untreated diagnosis: the condition usually will not improve, and may worsen. Patients with high levels of adherence incur lower overall medical costs and are less likely to be hospitalized.<sup>44</sup>

Given the known importance of appropriate medication use, rates of adherence and persistence remain astonishingly low. Adherence is estimated to be about 70 percent across disease states, lower in asymptomatic chronic conditions,<sup>45,46</sup> and varies by dosing regimen, from about 80 percent with once-daily dosing to about 50 percent with four-times-per-day dosing.<sup>47</sup> Estimates of mean persistence after 12 months of therapy range from 40 percent-70 percent.<sup>48, 49</sup>

Adherence and persistence can have a profound impact on therapy. For example, a physician who treats hypertension will likely increase a drug dose or add a second drug if a patient's blood pressure is inadequately controlled on initial therapy, which can increase the risk of drug interactions or adverse drug reactions. If, however, the reason for the uncontrolled blood pressure is related to nonadherence, improving adherence can result in adequate therapeutic response without the added risk or cost of additional drug therapy.

Part D plans can use the information available in a pharmacy claim database to retrospectively assess and monitor medication adherence and persistence. A variety of established methods for this type of evaluation are published and validated, each associated with potentially significant limitations (beyond the scope of discussion here), but selection of a uniform methodology will minimize their influence and allow comparison across Part D plans.

Proactive programs offer opportunities for Part D plans to improve adherence and persistence to chronic medications. As stated above, adherence and persistence can be measured based on prescription refill rates. Plans can identify patients who, having submitted at least one claim for a chronic medication, fail to submit subsequent claims for the medication within a specified time frame. This type of program is best accomplished using broad medication class definitions, to avoid flagging modifications in chronic therapy as incidences of nonadherence. Encouraging the use of mail-service pharmacies may also improve chronic medication adherence and persistence because of the increased availability of 90-day supplies.<sup>50</sup> Quality reporting should be adjusted for the frequency of mail service pharmacy use so that plans with more frequent mail service use do not have falsely elevated persistence compared to their competitors.

A standardized set of medications could be used to assess adherence and persistence among beneficiaries. These medications should have demonstrated long-term benefits, and may include:

- Antihypertensive agents, including angiotensin-converting enzyme inhibitors (ACE-inhibitors), angiotensin-receptor blockers (ARB) and beta-blockers.
- Long-acting respiratory medications, including inhaled corticosteroids.
- Psychotropic agents, including antidepressants and antipsychotics.
- Antihyperlipidemic agents, including HMG-CoA reductase inhibitors.
- Bisphosphonates used for osteoporosis.

## C. Adverse Drug Events

Adverse drug events (ADE) are common in elderly patients and patients with multiple comorbid conditions. ADEs that occur in this population have profound health and financial consequences. About one-third of elderly adults experience an ADE each year.<sup>51</sup>

### 1. Adverse Drug Reactions

There are two types of ADEs: adverse drug reactions (ADR) and drug interactions. An **adverse drug reaction** is an undesired effect that is causally related to the use of a medication, excluding accidental or deliberate misuse. ADRs are underreported and undertreated. Primary care providers are aware of approximately 50 percent of patient-reported ADRs.<sup>52</sup>

Accurate identification of ADRs is difficult without medical claim data. An adverse reaction that results in discontinuing a medication or modifying the medication regimen cannot be distinguished from nonadherence or discontinuation due to poor effectiveness using prescription claim data alone; however, Part D plans may assess several types of interactions using prescription claim data and use the findings as an estimate of overall ADR rates within their population. For example:

- A claim for an angiotensin-converting enzyme (ACE) inhibitor, followed within 90 days by a claim for an angiotensin-receptor blocker (ARB), without subsequent claim for an ACE-inhibitor.
- A claim for a nonsteroidal anti-inflammatory drug (NSAID), followed by a claim for a proton-pump inhibitor, H2-receptor antagonist or other GI-protective agents, within 90 days.
- A therapy change within 30 days of initiating treatment.

Part D plans can also use existing pharmacy claim technology and relationships with network pharmacies to identify patterns that suggest potential ADRs. For example, if a claim for an H2-receptor antagonist is submitted by the pharmacy following use of an NSAID, the pharmacist can be prompted to determine if an adverse event occurred and submit this information with the claim.

A significant role that Part D plans can play is data aggregator with regard to adverse events. Every physician or pharmacist encounters cases in which adverse events occur; however, large databases of information are often necessary to identify ADR trends between drugs. Using existing technology, a Part D plan can monitor and identify these trends, use the information for future formulary and benefit decisions, and communicate findings to CMS and the medical establishment at large.

## 2. Drug Interactions

A **drug interaction** is a therapeutic consequence that occurs when the action of a medication is altered by another drug or herbal product, ingestion of food or a concomitant disease state. Most drug interactions are undesirable because they decrease efficacy or increase the risk of an adverse reaction. Identification of drug-drug interactions in the near future will likely be limited to those identified through existing, standard, real-time DUR edits. Interactions are brought to the pharmacist's attention via automated messaging when a prescription is processed; however, the utility of drug-drug interaction software may be limited since it fails to detect clinically-relevant interactions up to one-third of the time.<sup>53</sup>

Plans should make every attempt possible (within data constraints) to identify drug interactions and notify the provider and the beneficiary, if appropriate. Processes should be based on best practices for effective intervention. Plans should be able to update interaction combinations in their systems and modify the drug interaction program to improve its effectiveness over time.

In addition to implementing standard, real-time DUR edits, Part D plans may affect the frequency of drug-drug interactions through retrospective prescription claim analysis. Plans may identify drug interactions within a patient's medication regimen and notify the patient, the patient's pharmacy or the prescriber. To focus the program on interventions that will benefit patients in the long-term and avoid overwhelming the prescriber or patient with inaccurate information, interactions should be limited to potentially serious ones between chronic medications. Examples of known interactions that Part D plans may implement to capture potentially serious interactions include:

- Chronic use of an acetaminophen-containing product and a medication that may increase the risk of acetaminophen-induced hepatotoxicity.<sup>a</sup>
- Concomitant use of carbamazepine and a drug that increases the risk of carbamazepine toxicity.<sup>b</sup>
- A dopamine agonist, used for Parkinson's disease and other neurologic conditions, with a dopamine antagonist such as haloperidol or metoclopramide.
- Lovastatin or simvastatin use with an agent that increases the risk of adverse effects, including amiodarone, diltiazem and verapamil.

<sup>a</sup> Carbamazepine, isoniazid, phenytoin and rifampin increase the risk of acetaminophen-induced hepatic toxicity.

<sup>b</sup> Diltiazem, fluoxetine, fluvoxamine, isoniazid, verapamil and many medications used in the treatment of HIV infection may increase the risk of carbamazepine toxicity.

**RECOMMENDATION:**

- *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 and processes and a few medication measures currently exist for Part D plans to begin clinical performance measurement.*

## SECTION IV: Care of Chronic Conditions

The Part D plan quality improvement and assessment program must be broad enough to encompass many dimensions of quality and the majority of beneficiaries. It must focus on more than disease-specific measures of quality, or its focus will be too narrow; however, chronic conditions are major drivers of morbidity, mortality and cost within the Medicare population. More than 75 percent of Medicare beneficiaries have at least one chronic condition, the most common of which are hypertension (51 percent), arthritis (37 percent) and heart disease (29 percent).<sup>54</sup>

Given the known benefits of appropriate treatment, a quality assessment measure set should include additional measures that focus on specific chronic conditions. Diseases and associated quality measures listed in this section illustrate quality assessment of specific disease states especially prevalent within the Medicare population.

### A. Cardiovascular Conditions

*(Congestive Heart Failure, Myocardial Infarction, Hypertension)*

The most common cardiovascular disease (CVD) states addressed in existing quality assessment and improvement tools are congestive heart failure (CHF) and myocardial infarction (MI).<sup>a</sup> Approximately 1 percent of the population 65 years of age or older is diagnosed with heart failure, and this condition consumes more Medicare dollars than any other diagnosis-related group (DRG).<sup>55</sup> Medication-related quality measures for heart failure consist primarily of measures of the rate of ACE-inhibitor and beta-blocker utilization. Similarly, outpatient measures of treatment following an acute MI focus on the frequency of beta-blocker and ACE-inhibitor prescription use upon discharge, and persistence of medication use. Plans participating in the MA program report HEDIS<sup>®</sup> quality measures related to use of beta blockers.

The Part D plan quality assessment program may include measures of hypertension and hyperlipidemia treatment and control. Hypertension is the most common diagnosis among Medicare recipients, affecting half of individuals 65 or older.<sup>56</sup> Adequate

Chronic conditions are major drivers of morbidity, mortality and cost within the Medicare population. More than 75 percent of Medicare beneficiaries have at least one chronic condition.

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<sup>a</sup> Of the 179 cardiovascular disease measures listed in the National Quality Measures Clearinghouse (<http://www.qualitymeasures.ahrq.gov>) in February, 2006, 63 (35 percent) addressed an aspect of congestive heart failure and 45 (25 percent) were related to acute myocardial infarction. Other measures related to cardiovascular disease concentrate on various aspects of coronary disease (29 measures), arteriosclerosis (24 measures) and hypertension (17 measures), although there is some degree of measure overlap between disease states.

antihypertensive therapy significantly reduces the risk of a cardiovascular event, but the rates of hypertension treatment and control are less than ideal among beneficiaries. In 2004, the rate of hypertension control among managed Medicare patients was 64.6 percent, an increase from 61.4 percent the previous year and 46.7 percent in 2000.<sup>57</sup> Lowering LDL cholesterol to goal levels is an integral component of primary prevention of coronary heart disease. Among patients with established coronary heart disease, appropriate reduction of LDL cholesterol significantly reduces the risk of a future cardiovascular event. In 2004, the rates of control within managed Medicare plans to LDL <130 mg/dL or LDL <100 mg/dL were 69.8 percent and 54.3 percent, respectively.<sup>58</sup> Because of the immense potential to improve health, Part D plans should support appropriate lipid management among their members.

Quality assessment related to medical management of CVD may be inhibited by difficulty extracting accurate diagnosis information using prescription claim data. Antihypertensive agents are used to treat a variety of cardiovascular conditions, including heart failure, arrhythmias and MI. Patient diagnosis information will likely be obtained and addressed via other mechanisms, such as beneficiary surveys or a medication management program. Measures applicable to many or all CVD states are useful for Part D plan quality assessment (refer to Exhibit 3 for examples). Since CVDs are so prevalent and costly for the Medicare program, CMS may want to identify beneficiaries with CVD and provide diagnosis information to the stand-alone Part D plans to help them take a more proactive role in managing their conditions. Part D plans can produce the short-term measures listed below without diagnosis or medical claim information.

Exhibit 3: Quality Measures for Cardiovascular Diseases

| Drug-Related Problem | Associated Quality Measures  |
|----------------------|--|
| Medication overuse   | <p><b>Short-term:</b></p> <ul style="list-style-type: none"> <li>• Frequency of therapeutic duplication (i.e., concomitant use of more than one agent from the same medication class).</li> <li>• Frequency of ingredient duplication.<sup>b</sup></li> <li>• Frequency of use of a calcium-channel blocker without other antihypertensive agent.</li> <li>• Frequency of short-acting calcium-channel blocker use.</li> <li>• Proportion of patients receiving beta-blocker monotherapy.</li> </ul> <p><b>Long-term:</b></p> <ul style="list-style-type: none"> <li>• Identification and prevention of hospital admissions related to hypotension.</li> </ul>   |
| Medication underuse  | <p><b>Short-term:</b></p> <ul style="list-style-type: none"> <li>• Beta-blocker adherence and persistence.</li> <li>• Adherence and persistence to ACE-inhibitor/ARB therapy.</li> <li>• Frequency of antihypertensive agent monotherapy.<sup>c</sup></li> </ul> <p><b>Long-term:</b></p> <ul style="list-style-type: none"> <li>• Proportion of patients with a diagnosis of heart failure or history of MI who are not receiving at least one cardiovascular medication.</li> <li>• Post-MI and heart failure patients receiving a beta-blocker.</li> <li>• Post-MI and heart failure patients receiving an ACE-inhibitor or ARB.</li> <li>• Percentage of patients with atrial fibrillation or flutter who take warfarin.</li> <li>• Patients with stable coronary artery disease or history of acute MI receiving a HMG-CoA reductase inhibitor.</li> <li>• Percentage of patients with chronic, stable coronary artery disease (CAD) who receive antiplatelet therapy.</li> </ul> |
| Adverse drug events  | <p><b>Short-term:</b></p> <ul style="list-style-type: none"> <li>• Frequency of use of an ACE-inhibitor and a potassium-sparing diuretic.</li> <li>• HMG-CoA reductase inhibitor use with verapamil or amiodarone.</li> <li>• HMG-CoA reductase inhibitor use with protease inhibitors.<sup>a</sup></li> <li>• Frequency of concomitant use of lipid-lowering medications and medications that may worsen the lipid profile, such as rosiglitazone and olanzapine.</li> </ul> <p><b>Long-term:</b></p> <ul style="list-style-type: none"> <li>• Identification and prevention of hospital admissions for hyperkalemia.</li> </ul>  |

<sup>a</sup> Pravastatin patients excluded.

<sup>b</sup> Ingredient duplication is especially concerning for cardiovascular medications, which are frequently available as combination products.

<sup>c</sup> Most patients with hypertension will require two or more antihypertensive medications to achieve therapy goals. Patients with heart failure and patients who have experienced a myocardial infarction should receive at least two antihypertensive medications: a beta-blocker and an ACE-inhibitor or ARB.

## B. Diabetes

More than 20 percent of adults 60 years of age or older have diabetes.<sup>59</sup> Patients with diabetes account for more than 40 percent of new cases of kidney failure and 60 percent of nontraumatic limb amputations each year. Appropriate diabetes treatment reduces the risk of MI, cardiovascular death and microvascular and neuropathic complications of diabetes.

The most common method of identifying patients with diabetes through a pharmacy claim dataset is to label patients as diabetic who have a claim for an oral hypoglycemic medication or insulin, but this method fails to identify patients with prediabetes or untreated type 2 diabetes, who comprise up to 30 percent of all diabetic patients. Patients with claims for oral hypoglycemic medications usually have type 2 diabetes, but may have another condition that is treatable with an oral hypoglycemic, such as the use of metformin for polycystic ovary syndrome. This assumption is further complicated by recent trials in which patients with type 1 diabetes were treated with oral hypoglycemic agents previously considered effective in only type 2 diabetes.<sup>60,61</sup>

Examples of measures that Part D plans could use to assess the quality of diabetes care are listed in Exhibit 4. Short-term measures listed can be produced by Part D plans without diagnosis or medical claim information.

Exhibit 4: Quality Measures for Diabetes

| Drug-Related Problem | Associated Quality Measures   |
|----------------------|---|
| Medication overuse   | <p><b>Short-term:</b></p> <ul style="list-style-type: none"> <li>• Use of two or more oral hypoglycemic agents within the same medication class.</li> <li>• Use of an oral hypoglycemic agent at higher-than-recommended dosage.</li> <li>• Use of chlorpropamide among patients 65 years or older.</li> </ul> <p><b>Long-term:</b></p> <ul style="list-style-type: none"> <li>• Identification and prevention of hospital admissions related to medication overuse, namely hypoglycemia.</li> </ul>  |
| Medication underuse  | <p><b>Short-term:</b></p> <ul style="list-style-type: none"> <li>• Adherence and persistence to oral hypoglycemic agent therapy.</li> <li>• Suboptimal utilization of diabetic testing supplies.</li> <li>• Patients with a claim for an oral hypoglycemic medication or insulin with claims for an antihypertensive agent but no claims for an ACE-inhibitor or ARB.</li> </ul> <p><b>Long-term:</b></p> <ul style="list-style-type: none"> <li>• Patients with a diagnosis of diabetes who are not receiving insulin or oral hypoglycemic agent therapy.</li> <li>• Proportion of patients with glycosylated hemoglobin value at or below the nationally-recognized treatment goal.</li> <li>• Proportion of patients with LDL-cholesterol value at or below the nationally-recognized treatment goal.</li> </ul> |
| Adverse drug events  | <p><b>Short-term:</b></p> <ul style="list-style-type: none"> <li>• Development of diabetes, indicated by an initial hypoglycemic agent claim, in patients who are taking medications known to worsen the glycemic control (e.g., corticosteroids, certain antipsychotic agents).</li> </ul> <p><b>Long-term:</b></p> <ul style="list-style-type: none"> <li>• Identification of ADRs, and associated interventions to address the reaction.</li> </ul>  |

### C. Mental Health Conditions

Mental health conditions are a significant concern within the Medicare population. About 5 percent of all beneficiaries meet criteria for depressive symptoms, and these patients are at least twice as likely to utilize medical inpatient and emergency department (ED) services than their nondepressed counterparts.<sup>62</sup> More than half of the beneficiaries under 65 experience symptoms of depression.<sup>63</sup>

In 2004, the average rates of effective treatment of depression were 56.3 percent and 42.1 percent in the 12 weeks and 6 months following diagnosis, respectively, for managed Medicare plans.<sup>64</sup> For mental health conditions, outcome is affected by many factors beyond the control and scope of the Part D plans. Given the complexity of these conditions, plans may be accountable for safety (e.g., interactions, toxicity) and adherence/ persistence measures. Examples of measures that may be used to assess the quality of mental health care are available in Exhibit 5. The short-term measures listed can be produced by Part D plans without diagnosis or medical claim information.

Exhibit 5: Quality Measures for Mental Health Conditions

| Drug-Related Problem | Associated Quality Measures  |
|----------------------|--|
| Medication overuse   | <p><b>Short-term:</b></p> <ul style="list-style-type: none"> <li>• Use of potentially-inappropriate psychotropic medications by elderly patients.<sup>a</sup></li> </ul> <p><b>Long-term:</b></p> <ul style="list-style-type: none"> <li>• Identification and prevention of hospital admissions for psychotropic medication toxicity.<sup>b</sup></li> </ul>   |
| Medication underuse  | <p><b>Short-term:</b></p> <ul style="list-style-type: none"> <li>• Antidepressant persistence for 12 weeks after initiation of therapy.</li> <li>• Antidepressant persistence for 6 months after initiation of therapy.</li> <li>• Identification of subtherapeutic dose, bearing in mind the often-reduced dosing requirements of the elderly population and excluding the first 90 days of therapy to allow for dose titration.</li> <li>• Detection of poor adherence to antiepileptic medication regimen, and associated intervention.</li> </ul> <p><b>Long-term:</b></p> <ul style="list-style-type: none"> <li>• Identification of untreated or undertreated psychiatric conditions, including depression.</li> </ul> |
| Adverse drug events  | <p><b>Short-term:</b></p> <ul style="list-style-type: none"> <li>• Identification and prevention of adverse drug-drug interaction that may lead to increased psychotropic medication toxicity.</li> <li>• Prevention of medication combinations associated with additive toxicity.</li> </ul> <p><b>Long-term:</b></p> <ul style="list-style-type: none"> <li>• Identification and prevention of health care utilization for adverse effects related to psychotropic medication toxicity.</li> </ul>   |

<sup>a</sup> Refer to Appendix III for a list of potentially-inappropriate medications covered under Medicare Part D.

<sup>b</sup> Psychotropic medications that may cause toxicity in elderly patients include: lithium, phenytoin, carbamazepine, valproic acid derivatives, opiates and benzodiazepines.

**RECOMMENDATION:**

■ *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.*

## SECTION V: Long-Term Quality Assessment

The majority of existing medication-related quality measures (refer to Appendix I) are designed to assess appropriate treatment of disease. Diagnosis and treatment information available in medical and pharmacy claim databases is essential for accurate calculation of most existing quality measures. Many health plans regularly use both types of data for quality improvement and assessment activities.

Within the current Medicare program, MA-PD plans have access to medical and pharmacy claim data. MA-PD plans undergo performance assessment using quality measures similar to those used to evaluate commercial plans; however, only 12 percent of Medicare beneficiaries are enrolled in an MA-PD plan.<sup>65</sup> Medical and pharmacy claims for the remaining beneficiaries 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 severely restricting evaluation of appropriate treatment regimen. Additionally, it is technologically difficult and costly to link medical and pharmacy claim databases. Even organizations that provide both benefits often use differing systems for their medical and pharmacy claims, thus limiting their ability to link and analyze such data.

This lack of easily-accessible medical claim and clinical data is the most significant barrier to a comprehensive quality improvement and assessment program for Part D plans. These plans may attempt to use member-reported diagnoses to improve treatment, but the accuracy of this method is questionable. Likewise, the use of pharmacy claim data to infer diagnosis is accurate for certain conditions, but is imprecise or impossible for others. Pharmacy claim data also fail to identify patients with untreated diagnoses – but these patients are often the most likely to benefit from interventions to encourage treatment.

Creating a dataset linking medical and pharmacy claim data is imperative for comprehensive quality assessment. Linking medical claims (Part A and Part B) to pharmacy claims will allow Part D plans to more accurately determine diagnoses and improve appropriate pharmacologic care. CMS should consider using a sample from a national dataset (e.g., 5 percent) and analyze claims from the Part A, B and D databases. Valuable information gleaned from such an analysis would help identify efficiencies in the systems and develop national solutions.

Creating a dataset linking medical and pharmacy claim data is imperative for comprehensive quality assessment. Linking medical claims (Part A and Part B) to pharmacy claims will allow Part D plans to more accurately determine diagnoses and improve appropriate pharmacologic care.

If Medicare provides Part D plans with diagnostic information and the Part D plans develop a more robust quality assessment capability, Medicare stakeholders must consider the expectations that accompany the availability and use of such data. What are reasonable expectations about how Part D plans should use these data? What are expectations about how treating physicians should act on these data? CMS holds MA plans accountable for collecting and acting on such information. What are the appropriate expectations within a fee-for-service delivery system and the implications for quality of care?

## A. Medication Overuse

### 1. Use Without Indication

Use without indication, or continued claims for a medication without an associated diagnosis, puts a patient at risk for adverse effects associated with the medication and does not provide tangible treatment benefits.

If the necessary medical data become available, plans will be able to assess appropriate medication use by cross-referencing medical (diagnoses) and pharmacy (medications) claims to identify medications without associated diagnoses. Activities and measures to assess the incidence of medication use without indication among beneficiaries include:

- Frequency of use of a high-cost or high-risk medication without an associated diagnosis.
- Frequency of use of certain psychotropic medications, especially atypical antipsychotic agents, without indication, or for an inappropriate indication.

### 2. Overdose/Toxicity

Drug-related problems associated with medication overdose and toxicity may include problems stemming from:

- Doses higher than recommended for patients, taking into account age, weight, interacting medications and concomitant disease states.
- Excessive duration of therapy.
- Therapeutic and ingredient duplication.
- Additive toxicity.

Many potential overdoses can be identified and avoided through existing edits in pharmacy claims processing. As quality assessment activities for Part D plans move forward, it may become possible to identify medical claims related to preventable medication toxicity. Plans may be able to track therapeutic laboratory monitoring of some medications for members at high risk of an adverse reaction or who have experienced a serious adverse reaction in the past. Quality measures to assess appropriate prevention of adverse effects related to medication overdose might include frequency of:

- Hospital admission for medication toxicity, by medication.
- Chronic warfarin therapy without appropriate laboratory monitoring (and similar measures for other medications requiring regular monitoring, such as clozapine).

### ***3. Improper Drug Selection***

Measures of inappropriate drug selection are another area to consider in the set of quality improvement activities and measures for evaluating Part D plans. These measures would promote appropriate medication selection based on nationally recognized treatment standards, such as those discussed in Section III of this document. Access to medical claim data is not absolutely essential for evaluating measures of inappropriate drug selection, but will help clarify a patient's diagnostic history.

## **B. Medication Underuse**

Medication underuse comprises three types of drug-related problems:

- Subtherapeutic dosage.
- Untreated indication.
- Failure to receive medication.

Subtherapeutic doses can be identified during claim processing with existing DUR edits, and retrospectively using pharmacy claim data. Systems necessary for implementing activities and measures based on existing DUR edits and pharmacy claim data are already in place and can be implemented in the short term. Future quality assessment of medication underuse may move into areas of untreated indications and failure to receive medication.

Managed care organizations (MCO) already use measures to identify and correct medication underuse. Part D plans may be able to engage in similar activities and measurement in the future. Examples of such measures include:

- Beta-blocker treatment and persistence after an acute MI.<sup>66</sup>
- Cholesterol management for patients with cardiovascular conditions.<sup>67</sup>
- Hypertension treatment and control.<sup>68</sup>
- Management of osteoporosis.
- Hospital admission rates for asthma, CHF, chronic obstructive pulmonary disease (COPD) and complications of diabetes in adults.<sup>69</sup>

## **C. Adverse Drug Events**

### ***1. Adverse Drug Reactions***

Many medication classes, including NSAIDs, antiplatelets, antiepileptics, hypoglycemic agents, diuretics, cardiac glycosides and beta-blockers, have been associated with preventable hospital admissions.<sup>70</sup> In most cases, appropriate prescribing and monitoring for adverse reactions can prevent hospital admissions and other medical claims for ADRs. Future quality assessment should include more robust prevention and monitoring of ADRs, which is currently accomplished via retrospective review of medical claim data. Individual plans develop their own specific programs.

ADRs among beneficiaries may be assessed as the frequency of hospital admissions with a primary diagnosis that is a known adverse reaction of a patient's medications. Examples may include:

- Hyponatremia, a known adverse effect of carbamazepine therapy, occurs in up to 21 percent of carbamazepine-treated elderly patients.<sup>71</sup> Appropriate monitoring may reduce the incidence of hospital admissions for hyponatremia among carbamazepine-treated patients.
- Antihypertensive medications, including hydrochlorothiazide, lisinopril, furosemide and medications with sedative effects, such as trazodone, increase the risk of hypotension and may increase the risk of falls.<sup>72</sup> Monitoring for hypotensive adverse effects may reduce hospital admissions for hypotension and falls.

## 2. Drug Interactions

Patients who receive medications with known, potentially serious adverse reactions and who are not monitored appropriately are significantly more likely to be admitted to the hospital than patients without interacting medications.<sup>73</sup> The importance of timing prescriptions cannot be emphasized too strongly when measuring drug interactions. Current programs that screen for drug interactions rely on historical prescription information matched against a newly dispensed prescription; however, this can result in false positives if the original drug is discontinued prior to initiating the new therapy.

Patients who receive medications with known, potentially serious adverse reactions and who are not monitored appropriately are significantly more likely to be admitted to the hospital than patients without interacting medications.

Assessing frequency and severity of drug-drug interactions within a Part D plan's

population may be accomplished by tracking hospital admissions or other health care utilization for medication toxicity and adverse effects caused by interacting medications. CMS could provide this data to Part D plans. Possible measures include:

- Patients using an ACE-inhibitor and potassium-sparing diuretic who are admitted to the hospital for hyperkalemia.
- Concomitant therapy with a HMG-CoA reductase inhibitor and a fibrate (gemfibrozil or fenofibrate), leading to rhabdomyolysis or acute renal failure.
- Diabetic patients admitted to the hospital for dysglycemia (hypo- or hyperglycemia), with a claim for gatifloxacin within the past 7 days.

### RECOMMENDATION:

- *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 these data and technical and cost issues related to creating the dataset.*

## SECTION VI: Barriers to Implementation of Quality Measurement

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**K**ee in mind that the majority of plans participating in Part D offer stand-alone pharmacy benefits. These plans will not have ready access to the clinical information necessary for measuring quality, including diagnosis, laboratory or radiological findings and information on use of other health care resources. This lack of both medical and pharmacy claim data severely restricts evaluations that assess the appropriateness of the treatment regimen and is the most significant barrier to a comprehensive quality improvement and assessment program for Part D plans.

### A. Noncovered Medications

Several classes of medications are excluded from Part D coverage, limiting Part D plans' ability to assess appropriate or inappropriate use of noncovered medications (see Exhibit 6). Plans may choose to assess noncovered medication use during assessment processes, such as medication therapy management; however, self-reported medication use may also be inaccurate. Among a sample of elderly members of a state pharmaceutical assistance program, only about half (49 percent) had perfect agreement between reported medications and pharmacy records. Of note, cardiovascular medications were less likely to be omitted than were other classes of medication.<sup>74</sup>

Stand-alone Part D plans must consider how to assess use of medications covered under the Part B benefit. Unless CMS provides utilization data, they may not have access to medical data and will have to rely on self-reported use. Utilization of medications that may be covered by Part B or Part D, depending on how they are dispensed and administered, will be difficult to assess.

Refer to Appendix III for a discussion of medication classes excluded from Part D coverage and the implications for plans that sponsor utilization management.

Exhibit 6: Classes of Medication Excluded from Part D Coverage

| Excluded Medication Class   | Impact on Quality Measurement   |
|---|---|
| Drugs for anorexia or weight loss   | Reduced ability to assess appropriate use of agents for weight loss, such as sibutramine and orlistat. May also impact assessment of amphetamine utilization; amphetamines are considered potentially inappropriate for elderly patients.   |
| Drugs used for weight gain  | Medications used for weight gain, most commonly megestrol, are appropriate for treatment of anorexia, cachexia or weight loss due to AIDS or cancer.  |
| Fertility medications   | Limited.  |
| Drugs for cosmetic purposes or hair growth  | Limited.  |
| Prescription vitamin and mineral products (except prenatal vitamins or fluoride preparations) | <p>Reduced ability to assess use of</p> <ul style="list-style-type: none"> <li>• Calcium supplements for osteoporosis or osteopenia. Iron supplements for iron-deficiency anemia, or as an adjuvant to erythropoietin therapy for anemia of chronic disease. Iron supplements in doses &gt;325 mg/day are considered potentially inappropriate medications in the elderly.</li> </ul>   |
| Nonprescription drugs   | <p>Reduced ability to assess:</p> <ul style="list-style-type: none"> <li>• Aspirin use for primary or secondary cardiovascular event prevention.</li> <li>• Tylenol or NSAID use for osteoarthritis or other pain conditions.</li> <li>• Utilization of nonprescription potentially inappropriate medications by elderly beneficiaries. These medications include cimetidine, mineral oil, stimulant laxatives (long-term use), long-acting NSAIDs, diphenhydramine and chlorpheniramine.</li> </ul>          |
| Barbiturates  | Limited. Given the wide variety of psychotropic medications available on the market, barbiturates have fallen out of favor for the treatment of many psychiatric illnesses. However, the lack of prescription claims will limit the plan's ability to screen patients for potential abuse.  |
| Benzodiazepines   | Will be unable to assess potentially inappropriate benzodiazepine use among elderly patients. Will also limit the plan's ability to screen for potential abuse of benzodiazepines.  |
| Drugs covered under Part A or Part B  | <p>Affected medications and (disease state) include:</p> <ul style="list-style-type: none"> <li>• Erythropoietin products, in certain administration circumstances (anemia).</li> <li>• Blood glucose monitors (diabetes).</li> <li>• Immunosuppressive drugs for rejection of an organ transplant.</li> <li>• Nebulizer treatments (asthma and COPD).</li> <li>• Certain oral anticancer drugs and antiemetic medications.</li> <li>• Enteral and parenteral nutrition (long-term care patients).</li> </ul> |

## B. Implementation Costs

Part D plans will maintain a database of member claims as part of the normal course of business. Querying this database using appropriate statistical software can be accomplished relatively easily and will be required in order to report plan metrics to CMS; however, quality improvement programs require resources. Interventions to encourage persistence and adherence will increase the plan's prescription drug costs, as will identification and treatment of previously untreated indications. Unlike MA-PDs, stand-alone Part D plans are not responsible for medical costs and therefore will not reap the savings associated with decreased hospitalizations or preventive care. Tangible and intangible costs must be considered during the development of a cost-effective quality assurance program. The primary tools available to plans involve clinical edits in the claims adjudication platform, point-of-service messaging, member communications, physician detailing and pharmacy network communication and education. The value of these actions is determined by the response the tool generates. For example, point-of-service messaging allows a plan sponsor to provide explanation and appropriate alternatives to the retail pharmacist — and, ultimately, the member — when a claim adjudicates in a particular manner due to a clinical edit.

In practice, the effectiveness of this tool is limited; the retail pharmacist may not receive the message or may disregard the message due to time constraints. Evaluation of potential measures must consider resources required of the stand-alone Part D plans in terms of material costs and program development, staffing, computer programming and service disruption, and intangible costs to members and retail pharmacists, such as frustration and time that may decrease potential effectiveness of a given measure.

CMS will need to be judicious in its requirements for measurement for efficient resource use — namely, Part D plans and pharmacists, physicians and beneficiaries' time and attention. Measures must meet the NQF criteria previously discussed or they will fail. Additionally, if pharmacists, physicians and beneficiaries are inundated with alerts and other communications, important safety warnings may go unnoticed or be ignored.

## C. Prescriber Identification

Prescriber identification is a significant barrier to analyzing prescription claims and the potential implications for Medicare Part D plans are significant. Inaccurate prescriber identification may result from illegible or unavailable prescription information; multiple prescribers using the same identifier; or pharmacist order entry error. At present, several types of prescriber identification are used. Each has its own limitations and potential for inaccuracy. Current forms of prescriber identification include:

- *DEA number.* Assigned by the Drug Enforcement Agency (DEA) to track prescribing of controlled substances, this identification number has become the standard method of identifying prescribers associated with pharmacy claims. Its use is limited due to restricted eligibility; inherent risk of fraud and abuse by access to the identification number; and use of the same DEA number by multiple prescribers within an institution.
- *State license number.* A license number is assigned by the applicable state board for each health professional; it is often used in lieu of a DEA number but has multiple limitations. The structure of the license number is not necessarily consistent between states, and prescribers licensed in multiple states will have a separate license number for each state. Many states do not have distinct numbering schemes between state boards, allowing multiple providers within a state to share the same license number issued by different state boards.
- *Unique Physician Identification Number (UPIN).* The UPIN is assigned by a CMS-designated contractor. It was required by Section 9202 of the Consolidated Omnibus Budget Reconciliation Act of 1985 for each Medicare Part B medical group physician and nonphysician practitioner reimbursed by Medicare. Limitations to this system include timeliness of assignment of the UPIN, as each provider must be appropriately certified by the CMS contractor, and limitations to the numbering scheme itself. The UPIN consists of six characters—an insufficient length to accommodate the quantity of unique identification numbers that would be required of a national standard identification number. Issues with data accuracy have been raised as a limitation to using UPIN as the national standard.<sup>75</sup>
- *Other identification numbers.* Health Industry Numbers and Health Identification Numbers (both known as HIN numbers) and Medicare and Medicaid provider numbers assigned by private organizations and federal and state government agencies were designed for specific purposes and have limited applicability and accuracy when used outside of their designated functions.

Part D plans are required to report both a prescriber identification and a prescriber identification qualifier on the prescription drug event (PDE) data that must be reported to CMS. Plan sponsor policies on submission of prescriber identification on claims may vary, with some plans requiring a DEA number when allowed by state law, and others requiring a state license number or UPIN if state law restricts use of the DEA number.

Pharmacies will be challenged to accurately and consistently submit prescriber identification based on each Part D plan sponsor's policy. This will also be a particular barrier to plan sponsor quality and management initiatives, such as academic detailing, prescriber notification and physician report cards, as there are no official data cross-walks between the three prescriber identification numbering systems to ensure accurate identification and correlation within the PDE data set and each Part D plan's pharmacy claim data.

Beginning in May 2007, all health care providers that are covered entities under HIPAA must obtain a National Provider Identifier (NPI). Health care providers that are not covered entities under HIPAA are not required to obtain an NPI; however, health plans may require eligible providers to obtain one as a condition for reimbursement.<sup>76</sup> The NPI will be assigned by a CMS-designated contractor, referred to as an enumerator, and the NPI assigned will be a standard, unique number.<sup>77</sup> This requirement will implement the first national standard for assigning a prescriber identification number and will significantly improve the ability of both medical and pharmacy claims payors to accurately identify the prescriber on any submitted claim. Because prescriber notification may play a key role in the quality assessment program for Part D plans, it will be vital that the prescriber is accurately identifiable from the prescription claim data.

## D. Quality Reporting to the Public

Due to growing costs and the large gap in quality in the health care industry as a whole, public reporting of health care quality is at an unprecedented level. NCQA has partnered with *U.S. News & World Report* to publish the List of the Nation's Best Health Plans, based on health plan accreditation and HEDIS<sup>®</sup> health performance measures. The purpose of this initiative is to make health plan quality and performance measures monitored by NCQA available to as broad an audience of consumers as possible, and to encourage more health plans to participate in this national set of quality and performance measures.

Consumer Reports publishes *Consumer Reports Best Buy Drugs*<sup>™</sup> in partnership with the Drug Effectiveness Review Project (DERP) at Oregon Health & Science University. AARP collaborates with DERP to provide efficacy, safety and cost information to members. These comprehensive, patient-focused cost and efficiency reviews are designed to help patients with chronic conditions optimize the value of their medication expenditures, and are available at no cost at [www.crbestbuydrugs.org](http://www.crbestbuydrugs.org) and [www.aarp.org/health](http://www.aarp.org/health).

Reporting to beneficiaries and the general public about plan performance must be accurate, meaningful and easily understandable for a lay audience. Performance metrics must be put into context and compared with national and regional benchmarks. Beneficiaries will need education to understand and use quality information about each Part D plan.

Beginning in 2007, Medicare beneficiaries can use comparative information to help them choose a Part D plan and compare their plan with other available plans. Public reporting may influence plan enrollment and encourage increased quality and benefit value. CMS must carefully consider how best to report plan performance information to beneficiaries and others.

Congressional oversight of the Part D program (the MMA requires CMS to report certain data on Part D plan performance to Congress) will be crucial to its continued success. As such, Congress and its related agencies (e.g., MedPAC, CBO) will need access to useful performance assessments.

Reporting to beneficiaries and the general public about plan performance must be accurate, meaningful and easily understandable for a lay audience. Performance metrics must be put into context and compared with national and regional benchmarks. Beneficiaries will need education to understand and use quality information about each Part D plan.

## SECTION VII: Quality Lapses in the Part D Program

Certain aspects of the Part D program leave beneficiaries vulnerable to lapses in health care quality. Inaccurate coordination of benefits may lead to a temporary decline in quality; cost-related declines in adherence and persistence during the coverage gap might lead to an overall decline in quality; changes in medication coverage from formulary modification or plan enrollment modifications may lead to a temporary decline in the quality of pharmaceutical care. Specific populations of Medicare beneficiaries are also vulnerable to quality lapses, including residents of long-term care facilities and traditionally underserved population subgroups.

### A. Quality Lapses Affecting All Beneficiaries

#### 1. Coverage Gap

Medication cost is a significant predictor of noncompliance. Part D prescription coverage may improve adherence among patients who were noncompliant for financial reasons prior to benefit implementation; however, noncompliance may reemerge during the coverage gap. Plans should actively monitor for lapses in adherence during the coverage gap, and continue the processes put in place to encourage adherence and persistence during this period.

#### 2. Continuity of Care

**Continuity of care** is a general term used to describe the process of transferring health information between providers. Continuity of care applies to all types of health care providers and is required in many health care settings, including inpatient facilities.<sup>78</sup> MMA created the Medicare Health Support program to help beneficiaries obtain the services they need, thus reducing lapses in care.<sup>79</sup> It applies mostly to transitions in health care, and falls into the “medication underuse” category of drug-related problems; however, problems may also arise when beneficiaries have multiple providers who are unaware of all the medications that have been prescribed. Part D beneficiaries will be most vulnerable on their initial enrollment into Part D, or during a change in plan enrollment or coverage limit.

Part D plans may assess the incidence of certain quality lapses related to continuity of care, including:

- The ratio of rejected claims to total claims during each member’s first month of plan enrollment. A disproportionate rate of rejected claims (compared to the regional benchmark) may suggest barriers to continuous medication use. Plans are currently not required to report overall rejected claim metrics to CMS; establishing this as an internal or additional quality measure may be important.

- The average time for approval or denial of a prior authorization or medical necessity medication request. Approval delays significantly longer than average are a hindrance to patients' receiving necessary medications.
- The average number of prior authorization or medical exception requests that a plan is unable to approve or deny due to lack of appropriate medical information. Excessive request turnaround times (e.g., 72 hours) are barriers to patient access.
- The number of claims rejected for prior authorization, step therapy or quantity limits that are not followed by a modified claim or request to the plan. A volume of unfulfilled claims that varies from the regional average may indicate lapses in medication use.

## B. Special Populations

### 1. Underserved Populations

The ethnic diversity of the American population continues to expand, with nearly 30 percent of adults identifying themselves as non-Caucasian in 2004.<sup>80</sup> In 1992, 14.1 percent of Medicare beneficiaries identified themselves as Hispanic or African American; by 2001, this number had increased to 16.5 percent.<sup>81</sup> In addition, the increasing longevity of the American population has impacted the dynamics of the Medicare population. From 1950 through 2004, the senior population grew twice as rapidly as the overall population, and similar growth is projected to continue until 2050.<sup>82</sup>

Such changes in the dynamics of the Medicare population have resulted in an older, more culturally diverse membership at a higher risk for racial and socioeconomic disparities. Disparities in the U.S. health care system are well documented. Part D plans should be accountable for quality of care for all beneficiaries, regardless of socioeconomic status.

### 2. Long-Term Care Patients

In 1998, CMS began the Nursing Home Quality Initiative by commissioning the University of Minnesota to conduct a study determining the feasibility of measuring quality of life for nursing home patients, with the objective of developing and testing measures and indicators of quality of life for nursing home residents. Study results were published in the report *Measures, Indicators and Improvement of Quality of Life in Nursing Homes*.<sup>83</sup> Findings were used as a tool for regulators in assessing nursing home quality, and by nursing homes in quality improvement efforts. The report was the framework supporting nursing home quality measures collected by CMS in the Minimum Data Set (MDS).

Current regulations require long-term care patients to receive a monthly medication review. Quality measures have been developed and tested that specifically examine the role of pharmacies or pharmacy professionals in assessing and monitoring long-term care drug therapy regimens to reduce potential drug interactions, ensure treatment response and improve overall quality of care. These measures should be adapted for Part D plans.

# Conclusions and Next Steps

Implementation of a prescription drug benefit for America's elderly and disabled populations represents a major step toward the goal of affordable, high-quality health care for all citizens. A centralized record of each beneficiary's prescription claim history will allow clinical interventions that may not have been possible before the introduction of Medicare Part D. For this program to achieve its potential, identification of appropriate quality assessment tools and use of meaningful measures will be essential.

How clinical performance measures are defined is critical to developing measures that will produce "the highest quality prescription drug benefits at the lowest possible cost."<sup>84</sup> Performance measures must be efficient and developed with a practical understanding of each segment of the benefit delivery system and its respective role, from plan sponsor and medical practitioner to retail pharmacist and beneficiary. This is an opportunity to look at accepted practices in the industry with a new eye; focusing on what will bridge the gaps between each segment of the benefit delivery system. It is also an opportunity to ensure that all available information is used to improve quality.

Consideration should be given to the already significant administrative burden placed on Part D plans. Performance assessment will most likely be implemented in progressive stages. The first stage can include measures that are validated in the literature and can be computed from readily available pharmacy claim data, or measures that require minimal claims data history to implement. Since they are currently in use within the industry, there are sufficient available data. These measures will expand and refine metrics already required and reported to CMS by plans and build on existing programs, such as MTM programs, step therapies, therapeutic interchange, utilization management, adherence and DUR programs.

The next stage would include new measures for which the following will be required:

- Testing and validation of proposed measures in Part D plans.
- Part D claims data experience greater than one year to evaluate.
- Additional evaluation and study of clinical literature.

Future performance assessment should include integrated medical and pharmacy claim data to accurately and comprehensively assess pharmacy benefit quality.

A centralized record of each beneficiary's prescription claim history will allow clinical interventions that may not have been possible before the introduction of Medicare Part D.

Limitations will affect how successfully the Part D program improves quality of care for Medicare beneficiaries, since stand-alone Part D plans will not have access to beneficiary medical history. CMS may choose to provide PDPs with additional medical claim data, particularly for high-risk beneficiaries such as those with CVD or diabetes. Other limitations involve benefit design. Overcoming these limitations will permit the creation of an accurate and thorough performance assessment program for plans, which will ensure that each Medicare-eligible patient benefits from high-quality prescription drug coverage under Medicare Part D.

The recommendations in this paper will benefit from further consideration by a multi-stakeholder advisory group and development of an implementation plan. The goal of this work should be a set of clinical performance measures appropriate for comparison of Part D plans that will focus plans on using data at their disposal for activities to improve the health of Medicare beneficiaries. The implementation plan and the final set of performance measures should take into account:

- Data available to all Part D plans.
- The nature of the relationship between Part D plans and other providers.
- Best practices on how to use pharmacy claims data with providers and patients.
- How to integrate with activities conducted through the Medicare Health Support program.

**RECOMMENDATION:**

- *A group of multi-stakeholder advisors 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.*

## APPENDIX I:

# Glossary of Quality Tools

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### **Academy of Managed Care Pharmacy (AMCP)**

<http://www.amcp.org>

The Framework for Quality Drug Therapy Management (Framework) is a comprehensive tool to measure and improve the quality of drug therapy within a practice setting or other organization. The Framework includes a self-assessment process that can be used by pharmacists or other health care providers to determine opportunities to improve the drug management process with the overall goal of achieving better outcomes. The Framework is designed not only to address issues surrounding drug therapies that are selected for patients, but also to expand beyond the individual patient to address the role of the health care system to promote the coordination of care and implementation of sound benefit policies that result in improvement in patient outcomes from drug therapy.

### **Agency for Healthcare Research and Quality (AHRQ)**

<http://www.ahrq.gov>

<http://www.qualitymeasures.ahrq.gov>

<http://www.guideline.gov>

AHRQ maintains the National Quality Measures Clearinghouse and the National Guideline Clearinghouse, searchable databases of validated quality measures and evidence-based clinical practice guidelines, respectively. AHRQ also publishes the National Healthcare Quality Report, which evaluates multiple dimensions of health care quality (safety, timeliness, patient-centeredness and effectiveness) and the National Health care Disparities Report, which measures quality and access to care across socioeconomic groups.

### **American College of Cardiology (ACC)**

<http://www.acc.org/quality/quality.htm>

ACC collaborates with other professional organizations, including the Physician Consortium for Performance Improvement (see below), to develop evidence-based guidelines for the management of various cardiovascular conditions. These documents, as well as performance measures for use in the treatment of hypertension, heart failure and coronary artery disease, are available through the ACC Web site.

## Centers for Medicare & Medicaid Services (CMS)

<http://www.cms.hhs.gov>

<http://www.medqic.org>

CMS administers a variety of quality assessment and improvement programs for beneficiaries of Medicare and Medicaid programs. The CMS Quality Initiative began in 2002, with the Nursing Home Quality Initiative, and has expanded with the Home Health Quality Initiative, the Hospital Quality Initiative, the End Stage Renal Disease Quality Initiative and the Physician Focused Quality Initiative. The Physician Focused Quality Initiative includes the Doctors' Office Quality project, which measures the quality of care for chronic disease and disease prevention in the outpatient setting and includes measures developed by NCQA and the Physician Consortium for Performance Improvement. Quality improvement organizations (QIO) aim to ensure that beneficiaries, especially underserved populations, receive quality health care through the Medicare program.

## Cochrane Collaboration

<http://www.cochrane.org>

The Cochrane Collaboration conducts rigorous, regularly updated, systematic reviews of literature pertaining to a variety of health-related topics. The Cochrane Database of Systematic Reviews is published quarterly and contains the majority of the Collaboration's research products.

## Institute for Safe Medication Practices (ISMP)

<http://www.ismp.org>

ISMP is devoted to safe medication use and medication error prevention. ISMP maintains a voluntary error-reporting program and publishes a biweekly error prevention newsletter.

## Institute Of Medicine (IOM)

<http://www.iom.edu>

IOM was chartered in 1970 to provide unbiased, evidence-based health information to policymakers. Two IOM reports, *To Err is Human: Building a Safer Health Care System* (2000) and *Crossing the Quality Chasm: A New Health System for the 21st Century* (2001) drew nationwide attention to quality lapses within the health care system. The IOM Pathways to Quality Improvement series covers three areas of quality improvement: measurement and reporting of performance data, payment incentives and quality improvement initiatives. A report on the first topic was published in early 2006; additional reports will be released later this year.

**Joint Commission on Accreditation of Healthcare Organizations (JCAHO)**

<http://www.jcaho.org>

JCAHO (or Joint Commission) is an independent, nonprofit accrediting organization and developer of health care standards. In 1997, it began an initiative to develop ORYX quality performance measures, designed to integrate outcomes and performance measurement data to create a comprehensive evaluation process. Users include integrated delivery systems, managed care organizations (MCO), managed behavioral health care organizations (MBHO) and preferred provider organizations (PPO). In 2002, the Joint Commission implemented additional measures for evaluating four standard performance indicators: rates of acute myocardial infarction, heart failure, pneumonia and complications of pregnancy. These performance measures are designed to encourage quality improvement among health care organizations, to benchmark quality among organizations and to track quality improvements within an organization.

**National Committee for Quality Assurance (NCQA)**

<http://www.ncqa.org>

NCQA began health plan quality assessment and accreditation in 1991. The accreditation program is the industry standard among MCOs, including commercial and managed Medicare and Medicaid plans. As part of the NCQA Accreditation process, health plans are required to calculate and report results of the Health Plan Employer Data and Information Set (HEDIS®), a standardized, validated tool to measure several dimensions of health care quality and service. The Quality Compass® database allows health care purchasers to compare HEDIS results across plans and obtain high-quality health care. NCQA also offers certification programs for physicians in diabetes, cardiovascular care and the routine use of clinical data to improve quality within their practice.

**National Quality Forum (NQF)**

<http://www.qualityforum.org>

NQF is a private organization that aims to improve health care quality by promoting and endorsing national, standardized health care performance measures and quality standards. Recent projects have focused on improving the quality of palliative care, ambulatory care, venous thromboembolism and cancer care.

**Physician Consortium for Performance Improvement**

<http://www.ama-assn.org>

Convened by the American Medical Association, the Physician Consortium for Performance Improvement (Consortium) develops performance measure sets to assess health care safety and quality in physician practice. The Consortium provides measurement sets for several disease states, including diabetes, asthma, osteoporosis and various cardiovascular conditions.

## **Study of Clinically Relevant Indicators for Pharmacologic Therapy (SCRIPT)**

The SCRIPT coalition, which comprises over 50 government agencies, pharmacy associations and health care groups, was initiated in 1998 to improve the quality of outpatient medication use. The coalition developed measures to assess medication utilization in 7 disease states: atrial fibrillation, coronary artery disease, diabetes, heart failure, hyperlipidemia, hypertension and myocardial infarction. The first phase of the project was managed by JCAHO and consisted of developing a method for selecting measures, including reviewing existing measures for validity and applicability. The second phase, managed by MassPRO, was characterized by field-testing measures related to medication prescribing and compliance, therapeutic monitoring and documentation of the 7 identified disease states. The final report was made to the IOM in March 2002.

## **Veterans Health Administration (VHA)**

*[www.oqp.med.va.gov](http://www.oqp.med.va.gov)*

*[www.pbm.va.gov](http://www.pbm.va.gov)*

The VHA Office of Quality and Performance assesses and improves health care processes and outcomes for beneficiaries through a variety of programs, including performance measurement and practice guideline development. The Pharmacy Benefits Management Strategic Health care Group (PBM SHG) provides various quality improvement tools related to the VHA pharmacy benefit, including medication class reviews, safety information and criteria for appropriate medication use.

## APPENDIX II: Medicare Part D Reporting Requirements Related to Clinical Quality<sup>a</sup>

| Category   | Reporting Element <sup>b</sup>  |
|--|---|
| <b>Medication therapy management programs (MTMP)</b>               | Number of beneficiaries who met MTMP criteria   |
|  | Number of beneficiaries who participated in the MTMP  |
|  | Number of beneficiaries who disenrolled from the MTMP   |
|  | Number of beneficiaries who declined to participate in the MTMP   |
|  | Total prescription cost of all medications for all beneficiaries participating in the MTMP, per MTMP member per month |
| <b>Generic dispensing rate</b>                                     | Number of paid claims for generic drugs   |
|  | Total number of paid claims   |
| <b>Prior authorization, step edits and nonformulary exceptions</b> | Number of pharmacy transactions rejected due to failure to complete step-edit requirements                            |
|  | Number of pharmacy transactions rejected due to need for prior authorization  |
|  | Number of prior authorizations requested for formulary medications  |
|  | Number of prior authorizations approved for formulary medications   |
|  | Number of prior authorizations requested for nonformulary medications   |
|  | Number of prior authorizations approved for nonformulary medications  |
|  | Number of prior authorizations requested for tier exceptions  |
| Number of prior authorizations approved for tier exceptions        |   |

<sup>a</sup> This table is adapted from Medicare Part D Reporting Requirements, updated 25 January 2006. A complete listing of reporting requirements is available in that document, which may be accessed at [www.cms.hhs.gov](http://www.cms.hhs.gov).

<sup>b</sup> Reporting elements listed in this table are reported quarterly, with the exception of MTMP elements, which are reported on a semiannual basis.

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# APPENDIX III: Potentially Inappropriate Medications and Medicare Part D Coverage

| Part D Exclusion Category                                       | Potentially Inappropriate Medications   | Rationale for PIM Classification   |
|---|---|--|
| Agents when used for anorexia, weight loss or weight gain.      | Amphetamines and anorexic agents, including: dextroamphetamine, methamphetamine, and methylphenidate.                               | Amphetamines and anorexic agents may cause dependence, hypertension, angina, and myocardial infarction. May suppress appetite in patients with anorexia or malnutrition, and have CNS-altering effects in patients with underlying cognitive impairment. |
| Agents when used for the symptomatic relief of cough and colds. | Antihistamines (chlorpheniramine and diphenhydramine).  | All non-prescription and many prescription antihistamines may have potent anticholinergic properties. Antihistamines without anticholinergic effects are preferred in elderly patients.  |
| Barbiturates (except Phenobarbital)                             | Decongestants when used in patients with bladder flow obstruction.  | May decrease urinary flow, leading to urinary retention.   |
| Benzodiazepines   | All barbiturates, except when used to control seizures.   | Barbiturates are highly addictive and cause more adverse effects than other sedative or hypnotic drugs in elderly patients.  |
|   | Short-acting benzodiazepines: doses greater than lorazepam 3mg, oxazepam 60mg, alprazolam 2mg, temazepam 15mg and triazolam 0.25mg. | Because of increased sensitivity to benzodiazepines in elderly patients, smaller doses may be effective as well as safer. Total daily doses should rarely exceed the suggested maximums.   |
|   | Long-acting benzodiazepines: chlordiazepoxide, diazepam, quazepam, halazepam, and chlorazepate.                                     | These drugs have a long half-life in elderly patients (often several days), producing prolonged sedation and increasing the risk of falls and fractures.   |
|   | Flurazepam (Dalmane).   | This benzodiazepine hypnotic has an extremely long half-life in elderly patients (often days), producing prolonged sedation and increasing incidence of falls and fracture. Medium- or short-acting benzodiazepines are preferable.                      |
|   | Long acting benzodiazepines in patients with stress incontinence.   | May cause polyuria and worsening of incontinence.  |
|   | Short- to intermediate-acting benzodiazepines used in patients with syncope or falls.   | May produce ataxia, impaired psychomotor function, syncope, and additional falls.  |
|   | Long-acting benzodiazepines used in patients with COPD.   | CNS adverse effects. May induce respiratory depression. May exacerbate or cause respiratory distress.  |

| Part D Exclusion Category             | Potentially Inappropriate Medications  | Rationale for PIM Classification   |
|---------------------------------------|--|--|
| Nonprescription drugs                 | <p>Anticholinergics and antihistamines: chlorpheniramine and diphenhydramine.</p> <p>Diphenhydramine (Benadryl).</p> <p>Ferrous sulfate&gt;325 mg/d.</p> <p>Long-term use of full-dosage, longer half-life, non-COX-selective NSAIDs, such as naproxen.</p> <p>Long term use of stimulant laxatives, such as bisacodyl and cascara sagrada, except in the presence of opiate analgesic use.</p> <p>Mineral oil.</p> <p>Cimetidine (Tagamet).</p> <p>Decongestants used in patients with bladder flow obstruction.</p> <p>Decongestants used in patients with insomnia.</p> <p>Pseudoephedrine and diet pills used in patients with hypertension.</p> <p>NSAIDs and aspirin (&gt;325 mg), coxibs excluded, used in patients with gastric or duodenal ulcers.</p> <p>Aspirin and NSAIDs used in patients with blood clotting disorders or receiving anticoagulant therapy.</p> | <p>All non-prescription and many prescription antihistamines may have potent anticholinergic properties. Antihistamines without anticholinergic effects are preferred in elderly patients.</p> <p>May cause confusion and sedation. Should not be used as a hypnotic. The smallest possible dose should be used for the treatment of anaphylactic reactions.</p> <p>Doses&gt;325 mg/d do not dramatically increase the amount absorbed but greatly increase the incidence of constipation.</p> <p>Have a potential to produce GI bleeding, renal failure, high blood pressure, and heart failure.</p> <p>May exacerbate bowel dysfunction.</p> <p>Potential for aspiration and adverse effects. Safer alternatives available.</p> <p>CNS adverse effects including confusion.</p> <p>May decrease urinary flow, leading to urinary retention.</p> <p>Concern due to CNS stimulant effects.</p> <p>May produce elevation of blood pressure secondary to sympathomimetic activity.</p> <p>May exacerbate existing ulcers or produce new/additional ulcers.</p> <p>May prolong clotting time, elevate INR values or inhibit platelet aggregation, resulting in an increased potential for bleeding.</p> |
| Propoxyphene and combination products | Offers few analgesic advantages over acetaminophen, yet has the adverse effects of other narcotic drugs.   | These medications are considered potentially inappropriate in elderly patients. Formulary alternatives include oxycodone/APAP and hydrocodone/APAP, as well as more potent single ingredient opioids.  |
| Indomethacin                          | Of all available nonsteroidal anti-inflammatory drugs, this drug produces the most CNS adverse effects.  | This medication is considered potentially inappropriate in elderly patients. Formulary alternatives include non-steroidal anti-inflammatory drugs with the lowest risk of gastrointestinal toxicity, including celecoxib, etodolac, ibuprofen, and nabumetone.   |
| Pentazocine                           | Narcotic analgesic that causes more CNS adverse effects, including confusion and hallucinations, more commonly than other narcotic drugs. Additionally, it is a mixed agonist and antagonist.  | This medication is considered potentially inappropriate in elderly patients. Formulary alternatives include full opioid agonists such as oxycodone/APAP and hydrocodone/APAP, as well as more potent single ingredient opioids.  |

| Potentially Inappropriate Medications Covered Under Medicare Part D  |  |   |
|--|--|---|
| Drug   | Concern  | Risks and Implications for Part D   |
| Muscle relaxants and anti-spasmodics: methocarbamol, carisoprodol, chlorzoxazone, metaxalone, cyclobenzaprine, orphenadrine, oxybutynin (excluding extended-release oxybutynin).               | Most muscle relaxants and antispasmodic drugs are poorly tolerated by elderly patients due to anticholinergic adverse effects. Their effectiveness at doses tolerated by elderly patients is questionable.         | These medications are considered potentially inappropriate in elderly patients. There are limited pharmacological alternatives that do not present similar risks for elderly patients.  |
| Amitriptyline, chlor diazepoxide-amitriptyline, perphenazine-amitriptyline   | Because of its strong anticholinergic and sedation properties, amitriptyline is rarely the antidepressant of choice for elderly patients.  | These medications are considered potentially inappropriate in elderly patients. Formulary alternatives include selective serotonin reuptake inhibitors (SSRI) with a lower risk of drug interactions and side effects, such as sertraline, citalopram and escitalopram. |
| Doxepin  | Because of its strong anticholinergic and sedating properties, doxepin is rarely the antidepressant of choice for elderly patients.  | This medication is considered potentially inappropriate in elderly patients. Formulary alternatives include SSRIs with a lower risk of drug interactions and side effects, such as sertraline, citalopram and escitalopram.   |
| Meprobamate  | This is a highly addictive and sedating anxiolytic. Patients using meprobamate for prolonged periods may become addicted and may need to be withdrawn slowly.  | This medication is considered potentially inappropriate in elderly patients. Formulary alternatives include buspirone. Several SSRIs and SSRI-like medications are also available with anxiety indications.   |
| Disopyramide   | Of all antiarrhythmic drugs, this is the most potent negative inotrope and therefore may induce heart failure in elderly patients. It is also strongly anticholinergic. Other antiarrhythmic drugs should be used. | This medication is considered potentially inappropriate in elderly patients. Formulary alternatives include quinidine and procainamide.   |
| Digoxin (should not exceed >0.125 mg/d except when treating atrial arrhythmias)  | Decreased renal clearance may lead to increased risk of toxic effects.   | This medication is considered potentially inappropriate in elderly patients. Patients who suffer from congestive heart failure and need digoxin reduction in hospitalization rates and increased exercise tolerance should not exceed the recommended dose.             |
| Short-acting dipyridamole. Do not consider the long-acting dipyridamole, which has better properties than the short-acting in older adults, except with patients with artificial heart valves. | May cause orthostatic hypertension.  | This medication is considered potentially inappropriate in elderly patients. Formulary alternatives should include clopidogrel.   |
| Methyldopa and methyldopa-hydrochlorothiazide  | May cause bradycardia and exacerbate depression in elderly patients.   | This medication is considered potentially inappropriate in elderly patients. Due to the multitude of antihypertensives currently available, there is limited utility for this older antihypertensive.   |

| Potentially Inappropriate Medications Covered Under Medicare Part D   |   |   |
|---|---|---|
| Drug  | Concern   | Risks and Implications for Part D   |
| Reserpine at doses >0.25 mg   | May induce depression, impotence, s edation and orthostatic hypotension.  | This medication is considered potentially inappropriate in elderly patients. Due to the multitude of antihypertensives currently available, there is limited utility for this older antihypertensive.   |
| Chlorpropamide  | It has a prolonged half-life in elderly patients and could cause prolonged hypoglycemia. Additionally, it is the only oral hypoglycemic agent that causes SIADH.  | This medication is considered potentially inappropriate in elderly patients. Formulary alternatives should include second generation sulfonylureas with a lower risk of prolonged hypoglycemia, such as glyburide, glipizide and glimepiride.   |
| Gastrointestinal antispasmodic drugs: dicyclomine, hyoscyamine, propantheline, belladonna alkaloids, clidinium-chlordiazepoxide | GI antispasmodic drugs are highly anticholinergic and have uncertain effectiveness. These drugs should be avoided (especially for long-term use).   | These medications are considered potentially inappropriate in elderly patients. There are limited alternatives for this class of agents.  |
| Anticholinergics and antihistamines: hydroxyzine, cyproheptadine, promethazine, triplennamine, dexchlorpheniramine              | All nonprescription and many prescription antihistamines may have potent anticholinergic properties. Nonanti-cholinergic antihistamines are preferred in elderly patients when treating allergic reactions. | These medications are considered potentially inappropriate in elderly patients. Formulary alternatives should include agents from the non-sedating antihistamine class, such as cetirizine, desloratadine and fexofenadine.   |
| Ergot mesyloids and cyclandelate  | Have not been shown to be effective in the doses studied.   | These medications are considered potentially inappropriate in elderly patients. Cyclandelate is no longer widely available. Formulary alternatives to ergot mesyloids include triptan agents (e.g., sumatriptan, eletriptan) and long-term preventative therapy for patients with chronic migraine concerns (e.g., beta-blockers, calcium channel blockers, anticonvulsants). |
| Meperidine  | Not an effective oral analgesic in doses commonly used. May cause confusion and has many disadvantages to other narcotic drugs.   | This medication is considered potentially inappropriate in elderly patients. Formulary alternatives should include other potent opioids such as morphine, hydromorphone and oxycodone.  |
| Ticlopidine   | Has been shown to be no better than aspirin in preventing clotting and may be considerably more toxic. Safer, more effective alternatives available.  | This medication is considered potentially inappropriate in elderly patients. Formulary alternatives should include clopidogrel.   |
| Ketorolac   | Immediate and long-term use should be avoided in older persons, since a significant number have asymptomatic GI pathological conditions.  | This medication is considered potentially inappropriate in elderly patients. Formulary alternatives should include nonsteroidal anti-inflammatory drugs with the lowest risk of gastrointestinal toxicity, including celecoxib, etodolac, ibuprofen and nabumetone.   |
| Daily fluoxetine  | Long half-life of drug and risk of producing excessive CNS stimulation, sleep disturbances, and increasing agitation. Safer alternatives available.   | This medication is considered potentially inappropriate in elderly patients. Physicians should consider every-other-day dosing or SSRIs with shorter half-lives, such as citalopram and escitalopram.   |

| Potentially Inappropriate Medications Covered Under Medicare Part D |   |   |
|---|---|---|
| Drug  | Concern   | Risks and Implications for Part D   |
| Amiodarone  | Associated with QT interval problems and risk of provoking torsades de pointes. Lack of efficacy in older adults. | This medication is considered potentially inappropriate in elderly patients. Cardioversion or nonpharmacological therapy may be necessary.  |
| Guanethidine  | May cause orthostatic hypotension. Safer alternatives available.  | This medication is considered potentially inappropriate in elderly patients. Due to the multitude of antihypertensives currently available, there is limited utility for this older antihypertensive.   |
| Guanadrel   | May cause orthostatic hypotension.  | This medication is considered potentially inappropriate in elderly patients. Due to the multitude of antihypertensives currently available, there is limited utility for this older antihypertensive.   |
| Isoxsuprine   | Lack of efficacy.   | This medication is considered potentially inappropriate in elderly patients. There is limited availability of this product and utilization is unlikely.   |
| Nitrofurantoin  | Potential for renal impairment. Safer alternatives available.   | This medication is considered potentially inappropriate in elderly patients. Formulary alternatives for urinary tract infections should include ciprofloxacin and sulfamethoxazole-trimethoprim.  |
| Doxazosin   | Potential for hypotension, dry mouth and urinary problems.  | This medication is considered potentially inappropriate in elderly patients. Formulary alternatives for hypertension should include diuretics, beta-blockers, calcium channel blockers, angiotensin converting enzyme inhibitors and angiotensin receptor blockers. Formulary alternatives for benign prostatic hyperplasia should include agents that specifically target alpha receptors in the prostate, such as tamsulosin. |
| Methyltestosterone  | Potential for hypertrophy and cardiac problems.   | Only a small subset of individuals with longstanding androgenic concerns would be subject to exposure to this drug. Topical androgen applications may present safer alternatives.   |
| Thioridazine  | Greater potential for CNS and extrapyramidal adverse effects.   | This medication is considered potentially inappropriate in elderly patients. First-generation antipsychotics are not agents of first choice because of their extensive side-effect profile, including potent anticholinergic effects. Formulary alternatives should include aripiprazole, olanzapine, quetiapine, risperidone and ziprasidone.  |
| Mesoridazine  | CNS and extrapyramidal adverse effects.   | This medication is considered potentially inappropriate in elderly patients. First-generation antipsychotics are not agents of first choice because of their extensive side-effect profile, including potent anticholinergic effects. Formulary alternatives should include aripiprazole, olanzapine, quetiapine, risperidone and ziprasidone.  |
| Short-acting nifedipine   | Potential for hypotension and constipation.   | This medication is considered potentially inappropriate in elderly patients. The use of short-acting dihydropyridine calcium channel blockers is no longer recommended. The long-acting formulation of nifedipine is an acceptable alternative.   |
| Clonidine   | Potential for orthostatic hypotension and CNS adverse effects.  | This medication is considered potentially inappropriate in elderly patients. Due to the multitude of antihypertensives currently available, there is limited utility for this older antihypertensive.   |

| Potentially Inappropriate Medications Covered Under Medicare Part D   |   |  |
|---|---|--|
| Drug  | Concern   | Risks and Implications for Part D  |
| Ethacrynic acid   | Potential for hypertension and fluid imbalances. Safer alternatives available.  | This medication is considered potentially inappropriate in elderly patients. The use of this loop diuretic is predominantly limited to patients with a sulfonamide allergy. Formulary alternatives for patients without a sulfonamide allergy include bumetanide, furosemide and torsemide.  |
| Desiccated thyroid  | Concerns about cardiac effects. Safer alternatives available.   | This medication is considered potentially inappropriate in elderly patients. Formulary alternatives should include levothyroxine formulations.   |
| Amphetamines (excluding methylphenidate hydrochloride and anorexics). | CNS stimulant adverse effects.  | These medications are considered potentially inappropriate in elderly patients. There is limited demand for these agents in an elderly population. If necessary, formulary alternatives should include methylphenidate formulations.   |
| Estrogens only (oral)   | Evidence of the carcinogenic (breast and endometrial cancer) potential of these agents and lack of cardio-protective effect in older women. | These medications are considered potentially inappropriate in elderly patients. Estrogenic agents should only be used during the perimenopausal period to aid in relief of menopausal symptoms. Long-term prevention or treatment of osteoporosis should be managed with formulary alternatives including calcitonin or bisphosphonates. |

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