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Toward Meaningful Quality and Performance Measures in Part D

A study conducted by staff from NORC at the University of Chicago, Georgetown University, and Social & Scientific Systems, Inc., for the Medicare Payment Advisory Commission

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NORC
at the UNIVERSITY OF CHICAGO

Report to the Medicare Payment Advisory Commission

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Executive Summary

MedPAC asked NORC to compile performance measures currently in use for Part D, as well as ideas for additional measures that might help beneficiaries make better plan choices or that might help CMS better oversee plans. This paper considers five domains of information that beneficiaries and policy-makers may want to know about Part D: access, quality and safety of care, costs, customer service and program administration, and overall satisfaction. We compiled measures from CMS and other ratings organizations, as well as ideas based on our own work tracking Part D plans for the first five years of the program.

Access to needed drugs. There are many possible ways to measure whether beneficiaries have access to medications, but more research is needed on how formulary-based measures can be used to create a prospective measure that would supplement retrospective measures of access.

Quality and safety. Many quality measures have been developed by organizations dedicated to that task. These include measures of adherence to recommended courses of medication, as well as avoidance of high-risk drugs and drug combinations. Plan formulary design and medication therapy management programs may be able to influence all of these factors.

Beneficiary and program costs. Premiums are an easily available measure of costs that can be used to compare plans. But much more could be understood about how plans perform on individual measures that contribute to overall costs, including price increases, mechanisms for steering beneficiaries to lower-cost drugs, out-of-pocket costs, and rebates.

Customer Service and Program Administration. In this domain, we consider the many measures that describe the quality of a plan's administrative processes, including how well the plan provides information to beneficiaries, providers, and pharmacists, the level of complaints about the plan, and problems uncovered in CMS audits and fraud and abuse reports.

Overall satisfaction. Currently, beneficiary-reported satisfaction is one measure among many others in the CMS plan rating system. It may be that this single measure could be the simplest and easiest to understand and could be highlighted to other beneficiaries seeking to choose a plan.

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Toward Meaningful Quality and Performance Measures in Part D

In the fifth year of Medicare's Part D prescription drug program, more information is available than ever before on how the program is working and what it costs. This baseline of information provides the opportunity to assess how to best measure plan performance, for the dual purposes of program monitoring and improvement, and helping beneficiaries to make informed choices among Part D plans.

CMS currently maintains a set of 19 performance measures on its website (a complete list is in Appendix A).¹ The agency publishes a precise rating for each Part D contract (typically a single organization that acts as a plan sponsor) on these measures unless there is not enough data to calculate a measure; in addition, it converts each of the measures into a star rating (one to five stars). On the Medicare Drug Plan Finder, CMS makes available a summary star rating for each of four domains (drug plan customer service, member complaints, member experience, and drug pricing and patient safety) as well as an overall summary star rating (one to five stars, with half stars used). CMS has recently posted some additional measures on its website either as supplemental measures or as trials for future incorporation into the summary measures (also included in Appendix A).² CMS also uses numerous other measures internally for monitoring Part D plans.

MedPAC asked NORC and Georgetown University to compile these current performance measures as well as ideas for additional measures that might help beneficiaries make better plan choices or that might help CMS better oversee plans. In this paper, we consider five domains of information that beneficiaries and policy-makers may want to know about Part D:

- **Access to needed drugs.** Can beneficiaries get prescribed drugs when they need them?
- **Quality of care (including safety).** Are beneficiaries getting their prescriptions filled without errors, and with appropriate oversight to ensure that they are not taking drugs that are harming them?
- **Beneficiary and program costs.** How do beneficiaries' costs compare across plans? How do the government's costs compare across plans?

¹ See also the discussion in *Report to the Congress: Medicare Payment Policy*, MedPAC, March 2010, pp. 300-302.

² CMS, "Part D Medicare Plan Ratings Display Measures (v03.30.10)." Accessed at http://www.cms.gov/PrescriptionDrugCovGenIn/06_PerformanceData.asp

- **Administration.** Does the plan operate in a way that fosters satisfaction among beneficiaries, pharmacists, and physicians, providing them with the information they need, resolving problems quickly when they arise, and using procedures that prevent problems from arising in the first place?
- **Overall satisfaction.** Taking all of these factors into account, how satisfied are beneficiaries with their Part D plan?

There is an inherent tension between some of these domains. For example, fewer utilization management restrictions on a plan's formulary may create the greatest possible access. But some restrictions might steer beneficiaries to lower-cost drugs, or protect them from receiving drugs that might harm them. Similarly, beneficiary and program costs may sometimes trade off against one another (although there should not be large trade-offs, within the structure of actuarial equivalence established for Part D), or against other measures.

Another complication in measuring some of these concepts is the question of what Part D plans can fairly be held accountable for. This is particularly an issue for stand-alone Part D plans, which have no control over any of the rest of a Medicare beneficiary's care and little influence over the physicians who prescribe drugs for their enrollees. But even in Medicare Advantage plans, there is a wide variation in the amount of communication and control between plans and the physicians serving their enrollees. We explore this question as we discuss many of the possible measures of plan performance throughout this paper.

Finally, when considering measures, it is important to consider the audience. There may be some measures of plan performance that are useful in monitoring plan behavior that are not particularly meaningful to beneficiaries. As CMS refines its oversight of Part D, it may want to consider narrowing the scope of the information presented to Medicare beneficiaries shopping for a plan, at the same time that the tools available for administrative monitoring of plans are expanding. This distinction may become even more important if CMS decides to exercise its authority to selectively contract with plans based on plan quality. Throughout this paper, we refer back to the question of whether a particular measure is of interest to beneficiaries, for program oversight, or for both purposes.

Sources of Data

There are now numerous sources of data available on Part D plans. In this section, we review some of the pros and cons of each type of data. In the next section, we examine some of the specific measures that might draw on these data sources.

Formulary and benefit structure. This is the only information about plans that is available prospectively, allowing beneficiaries and CMS to potentially judge the plan on access and cost factors for the coming plan year. CMS also compares the prices that plans provide to actual prices to measure the accuracy of the data they submit for the Plan Finder. However, there are challenges in using any of these measures in the absence of other information, as we discuss in the next section.

Part D claims. Claims data provide additional insight into how many prescriptions beneficiaries are filling, and at what cost. There can be a significant lag time before claims are available for outside analysis – making it difficult for researchers outside CMS to judge plans’ future performance, particularly if plans have changed their formulary, benefits, or administrative policies. Further research could be done into how claims data correlate with other measures of plan performance that are available closer to real time.

Alternatively, it may be possible to develop methods for working with claims data that do not require adjudication and reconciliation of prices and payments. At least within CMS, it might be possible to review claims data on a more real-time basis to draw conclusions about some aspects of plan performance. For example, CMS staff might be able to analyze data from the first 6 months of the year in time to influence contracting decisions for the following benefit year.

Claims are also limited because they may not provide a full account of drug use. For example, if beneficiaries receive drug samples, purchase drugs off formulary, or shop for drugs outside their Part D plan, this utilization will not show up in drug claims. This gap in data will need to be considered when using claims data to describe utilization patterns.

Part D claims linked to Part A and B claims. Linking to claims for physician and hospital use opens up further possibilities for measurements of plan quality. For example, measures of utilization can be limited to beneficiaries with certain diagnoses or patterns of health care use. Likewise, patterns of health care use – such as emergency room visits – can be examined for the effects of different incentives for drug use. It is worth noting that Part A and B claims are not currently available for beneficiaries enrolled in Medicare Advantage plans; CMS intends to require plans to submit these data starting in 2012. Like drug claims, Part A and B claims have a significant lag time associated with claims adjudication, but it might be possible to use un-

adjudicated claims as a source of information about beneficiary hospitalizations or other resource use, if cost data are not needed.

E-prescribing data. Claims data can provide information on what prescriptions were filled, but they do not include information on how many prescriptions might have been written but not filled – possibly a sign that plan policies are creating barriers for their enrollees. The information collected by e-prescribing systems would be the best way to measure the number of prescriptions that are originally written. While CMS has promulgated standards that plans must follow with their connectivity to e-prescribing, it does not appear that CMS currently collects any information that is available from e-prescribing systems. However, some researchers have used e-prescribing data as a way to measure adherence by patients.³

Plan-reported data. Plans are required to submit to CMS certain performance measures on a quarterly basis. This makes these data a good source of measures that are closer to real time. CMS is currently implementing new requirements that plans hire outside auditors to examine the information submitted, which should improve the validity of the data. But they also have some drawbacks, such as the fact that they are reported at an aggregate contract rather than an individual plan level. Some activities conducted at the organizational sponsor level, such as the operation of call centers, cannot be measured at the plan level. But for measures on the use of exceptions or responses to beneficiary satisfaction surveys might be most meaningfully measured at the plan level (or at least for the same plan aggregated across regions).

Consumer Assessment of Healthcare Providers and Systems (CAHPS). CAHPS surveys ask Medicare beneficiaries about experience with their health plans – including both stand-alone PDPs and Medicare Advantage plans. In 2009, the sample included 690,000 Part D enrollees. Data appear to be available less than a year after they are collected.⁴

Other CMS administrative data. In addition to the sources of data listed above, CMS has a few others. These are generally not publicly available, except in aggregate form as CMS uses them for plan measures on its website:

- **Information from the Independent Review Entity.** Beneficiary problems that are not resolved internally by a Part D plan can be sent to an Independent Review Entity (IRE). The IRE shares data with CMS on the resolution of cases. At a very detailed level, this provides CMS with opportunities to follow up with plans that appear to be pursuing

³ Joshua N. Liberman, David S. Hutchins, Richard G. Popiel, Mihir H. Patel, Saira A. Jan, and Jan E. Berger, “Determinants of Primary Nonadherence in Asthma-Controller and Dyslipidemia Pharmacotherapy.” *American Journal of Pharmacy Benefits* Volume 2 (2010): 111-118.

⁴Liz Goldstein. “CMS CAHPS Surveys: Public Reporting.” Slide Presentation from the AHRQ Annual Conference (2009). <http://www.ahrq.gov/about/annualconf09/goldstein.htm>

inappropriate policies; on a more global level, statistics about cases are used as part of CMS's plan ratings.

- **Complaints about drug plans.** Beneficiaries, providers, and pharmacists can also complain directly to CMS about drug plans. CMS maintains data on these complaints and uses this to monitor plan performance in multiple domains.
- **Call center information.** CMS monitors Part D plan call centers for responsiveness and accuracy by randomly placing calls. This monitoring is done at the plan sponsor level.
- **Enrollment and disenrollment.** Disenrollments can be tracked in CMS's administrative systems to monitor for problems with a particular plan. CMS also monitors transactions related to enrollment and disenrollment in the Medicare Advantage Prescription Drug System (MARx) for timeliness and accuracy, and compares plan-provided data on enrollment to CMS's own information, to check for accuracy.
- **Plan audits.** CMS audits plans periodically, and reports aggregate audit findings as a measure.

Measuring Access to Medications

There are many possible ways to measure whether beneficiaries have access to medications. Measures derived from a plan's formulary need to be more refined, but they are the most forward-looking, using information directly relevant to the next plan year. Other measures that could be used retrospectively include information on plans' decisions regarding utilization management requirements, coverage determinations, exceptions, and appeals; claims data on whether beneficiaries use specific drugs in specific recommended situations; beneficiaries' own reports of whether they can easily access their medications; measures of a plan's pharmacy network; and measures of timeliness in filling prescriptions.

Formulary Measures

In the beginning of the Part D program, CMS offered beneficiaries a measure of how many of the top 100 drugs were listed on formulary by each Part D plan. In the absence of other measures of access, this metric offered some information about plan coverage beyond the specific drugs they were already taking at the time of open enrollment. The total number of drugs on a plan's formulary is an intuitively appealing measure of access to prescriptions: presumably, the more drugs on formulary, the better the access. But as we have tracked plan formularies over five years, it has become clear that formulary listings are not so easily equated to access.

Even when a drug is on formulary, coverage may be restricted. Utilization management tools such as requirements for prior authorization or step therapy require beneficiaries and their physicians to fulfill certain requirements before the plan will cover the drug. In focus groups with physicians, many said they would rather prescribe another drug than go through the prior authorization process.⁵ Placement of drugs on tiers with high cost sharing, and limits on the quantity of the drug that may be dispensed may restrict access in other ways. At the same time, even when drugs are off formulary, there are certain circumstances when coverage may be possible through exceptions or transitional supplies.

Plans may use these management tools in different combinations both to encourage use of clinically appropriate drugs and to establish leverage for negotiating with manufacturers for lower prices. It is difficult to tell whether certain combinations result in more or less access to drugs. For example, some plan sponsors place all drugs on formulary and use tools such as tier placement and prior authorization heavily. Other plan sponsors leave many drugs off their formularies, but say that they have relatively simple exceptions processes to grant beneficiaries access to the drugs that are not on formulary.

To address some of these differences, we have developed a measure of formulary coverage that divides a plan's treatment of drugs into two categories: restricted and unrestricted, in which restricted drugs include drugs that are either on a non-preferred brand tier, on a specialty tier, or subject to prior authorization, step therapy or quantity limits.⁶ However, this still leaves unmeasured factors such as the ease of obtaining formulary exceptions.

Further research could be done on claims patterns to determine how utilization patterns vary under different combinations of formulary placement and utilization management, to give additional insight into how these different elements of plan design affect access. Ultimately, it might be possible to design a measure based on plan formulary design that would have predictive power – giving beneficiaries a meaningful measure of access that they could use during an open enrollment period to help guide their plan choice for the next year.

To explore this concept, we tested the correlation of some basic formulary measures with other measures of plan quality and access that are published for use with plan selections for 2010 (Table 1). The total number of drugs on formulary in 2010 is uncorrelated with the overall star

⁵ Elizabeth Hargrave, Jack Hoadley, Laura Summer, Bhumika Piya, and Jen Thompson. *Experiences Obtaining Drugs under Part D: Focus Groups with Beneficiaries, Physicians, and Pharmacists*. Report to the Medicare Payment Advisory Commission. No. 08-4. May 2008.

⁶ For more information on how this measure was derived, and results of how many drugs typically fall into these categories, see *Medicare Part D Formularies, 2006-2010: A Chartbook*, at www.medpac.gov.

rating published by CMS for 2010 plan selections, but it is positively correlated with the CAHPS survey measure of whether plan enrollees believe it is easy to fill prescriptions (based on data collected by CMS in February to June 2009). By contrast, our measure of unrestricted drugs is positively correlated with the overall star rating, but less correlated with enrollees' perception that they are getting needed drugs. Both measures are correlated with enrollees' overall satisfaction with their plan (based on data collected from February to June 2009). Conversely, the use of prior authorization (PA) is associated with lower ratings on all three measures. None of our formulary measures were strongly correlated with a more targeted measure of access that we discuss below, the number of people who take a diabetes drug who also take a drug to control their blood pressure (based on drug claims for 2008). (The use of blood pressure medications is recommended for individuals with diabetes as a way to help prevent kidney disease.)

Table 1. Correlations between Plan Formulary Measures and Other Measures of Satisfaction and Access

	Overall star rating on CMS Plan Finder	Member rating of satisfaction with plan	Member rating of ability to fill prescriptions	People taking a diabetes drug also taking a blood pressure drug
Total number of drugs listed on formulary	-0.05	0.28	0.49	0.01
Number of unrestricted drugs on formulary	0.57	0.34	0.18	0.02
Drugs with any UM	-0.45	-0.15	-0.01	0.01
Drugs with PA	-0.27	-0.34	-0.33	0.04
Drugs with QL	-0.41	-0.08	0.03	-0.05
Drugs with ST	-0.23	0.18	0.20	-0.14

SOURCE: NORC/Georgetown/SSS analysis of plan ratings for 2010 and 2010 plan formulary files. Plan ratings are available on CMS Plan Finder website, <http://www.medicare.gov/find-a-plan/questions/home.aspx>.

Further information about NORC/Georgetown/SSS analysis of plan formularies is available in *Medicare Part D Formularies, 2006-2010: A Chartbook*, at www.medpac.gov.

Decisions Related to Utilization Management

Through plan quarterly reports (at the contract level), CMS tracks the number of transactions rejected by the plan due to prior authorization, step therapy, and quantity limits. Plan sponsors also report the number of prior authorizations requested and approved, and the number of other exceptions to utilization management restrictions that are requested and approved.

Just as there are challenges in making overall formulary measures meaningful, these measures also provide challenges. The number of drugs subject to prior authorization in a plan clearly will have an effect on the number of requests for authorization, and it may also have an effect on the share of requests that are approved. Just as with formulary coverage, some plans may simply have a different philosophy about the role of these utilization management techniques, which can be fairly expensive to implement. Plans may use them as for a method of cost control for expensive drugs, as a safety check for potentially dangerous drugs, or as an administrative check (e.g., checking whether a drug is eligible for Part D versus Part B coverage). A plan might have a high approval rate if it is fairly generous in its disposition of requests, but also if it discourages requests in all but the most compelling cases or if it uses prior authorization primarily for administrative issues that will mostly lead to approvals. Thus, it may be difficult to determine whether different rates of approval have any meaning for comparing plans.

Currently, rather than using these measures to rate plans, CMS uses them as a monitoring tool at the contract level. If they were ever to be used for beneficiary information, it seems that they would be more helpful at the plan level, since some of these factors may vary with a plan's formulary. However, more work would be needed to define measures that fairly represented the relative restrictiveness of different plans.

Another set of information that might be helpful to know about plans would be their policies related to utilization management when beneficiaries are transitioning from one plan to another. For example, some plans may allow a beneficiary to continue taking a medication that requires prior authorization if it had already been authorized by another plan; others may require the beneficiary to obtain a new authorization. This information might be especially useful when beneficiaries consider making a switch during the open enrollment period to a less expensive plan.

Decisions Related to Coverage Determinations, Exceptions, and Appeals

In addition to reporting on decisions related to utilization management, plans report on how many transactions are rejected due to non-formulary status, the number of formulary exceptions requested and approved, and the number of tier exceptions requested and approved. Finally, plans must report on the number of appeals that resulted in

redeterminations, and the number resulting in a full or partial reversal of the plan's initial decision.

CMS also receives data from the Independent Review Entity (IRE), which is currently a company called MAXIMUS. Two measures from those data are used in the star rating for the "drug plan customer service" domain on the Plan Finder: the rate of cases forwarded to the IRE because the plan did not make a coverage determination or redetermination on time; and the percent of IRE confirmations upholding the plan's decision.

CMS has access to other information from the IRE that it can review on a case-by-case basis for plan monitoring. In the supplemental measures currently available on the CMS website, there are two additional appeals-related measures: the percentage of cases for which the IRE receives case files from the plan in a timely manner, and the percentage of cases for which the plan implements the appeals decision in a timely manner.

Finally, plans are required to report the total number of grievances they receive from enrollees, by topic; one topic area covers the coverage determinations/exceptions and appeals process. For example, an enrollee can file a grievance if he or she disagrees with a plan's decision not to expedite a request for a coverage determination or redetermination. (However, grievances do not cover the outcomes of a coverage determination or redetermination; those complaints go through the IRE process.) Plans are also required to report on the number of grievances for which the plan provided timely notification of a decision. As far as we can determine, however, they are not required to report on the outcome of their decisions.

Adherence Measures

Whether a beneficiary fills a prescription – or continues to refill it over time – can be influenced by various factors. Many of these factors, such as side effects, complex regimens, cognitive issues, and lack of social support, are outside the control of a prescription drug plan. Furthermore, without looking at a medical record, it is difficult to discern whether a failure to fill a prescription is due to a barrier to use, or a change in the patient's treatment plan.

However, after taking all of these limitations into effect, measures of adherence might still play a useful role in measuring access. If the other factors influencing adherence could be assumed to be evenly distributed across plans, then differences among plans in adherence could be attributed to plan design or plan policies. A more nuanced approach might attempt to adjust adherence measures for other known characteristics of enrollees that are correlated with differences in medication use and adherence. It might be especially important to distinguish between adherence rates of low-income subsidy (LIS) and non-LIS populations because of

differences in program design and other factors that may affect adherence differently.⁷ CMS could also look for changes in adherence associated with changes in plan policies, such as tier status or prior authorization requirements.

We reviewed measures of adherence from many organizations that seek to measure quality and performance of health plans, pharmacy benefit managers, and health care providers, including the National Quality Foundation (NQF), the Pharmacy Quality Alliance (PQA), URAC (an organization that accredits PBMs), and AHRQ's National Quality Measures Clearinghouse (NQMC), which includes measures from such organizations as the American Medical Association (AMA), the National Committee for Quality Assurance (NCQA), and other organizations. Measures of adherence often follow into several general categories.⁸

Medication Possession Ratio (MPR) and Proportion of Days Covered (PDC): The number of days of medication supplied, divided by the number of days in the study period.⁹ For example, URAC includes among its quality measures for PBMs the overall MPR for new patients, continuing patients, and all patients, in both mail service and specialty pharmacy. The Pharmacy Quality Alliance (PQA) and the National Quality Forum (NQF) both use measures that look for patients above and below a threshold of 80% of days covered for particular medications. Another NQF measure looks at whether patients continue to take a certain drug for at least 135 days out of the 180 days immediately following a hospital discharge.

Measures of Medication Gaps: The number of days in the gaps between refills, or the number of gaps of a certain length. For example, several measures endorsed by the Pharmacy Quality Alliance (PQA) look at the percentage of users of a medication who experience a gap of at least 30 days in therapy.

Measures of Persistence: Proportion of patients refilling prescriptions a certain number of times, or continuing to take for a certain number of days.

⁷ For example, one study has found lower prevalence of medication use among LIS diabetics, despite their lower cost sharing. See Bruce Stuart and Linda Simoni-Wastila, "Monitoring Chronic Disease Care and Outcomes among Elderly Medicare Beneficiaries with Chronic Disease." Report to CMS, November 25, 2009. http://www.cms.gov/Reports/Downloads/Stuart_MRAD_Final_Report_2009.pdf

⁸ Andrew M. Peterson, David P. Nau, Joyce A. Cramer, Josh Benner, Femida Gwadry-Sridhar, and Michael Nichol. "Report of the ISPOR Medication Compliance & Persistence Special Interest Group: A Checklist for Medication Compliance and Persistence Studies Using Retrospective Databases." *Value Health* 10, no. 1 (2007): 3-12. Accessed at http://www.ispor.org/workpaper/research_practices/Peterson%20Scientific%20Report.pdf

⁹ MPR may be calculated for a consumer's entire drug regimen, so that the MPR can be greater than 100%; the PDC typically looks only at a single medication and can never be more than 100%.

Measures of adherence across all drugs could be a starting point for a global measure of access. However, as we discuss in the section on quality and safety, not all medication use is necessarily good. A more nuanced approach would be to focus on utilization and adherence in specific cases that have been identified as indicators of quality of care. In general, these measures look for the use of specific types of drugs, among beneficiaries with specific conditions. In our review of adherence measures, we identified over 100 such measures (with some significant overlap among them), included in Appendix B. Some examples include:

- Use of angiotensin-converting enzyme (ACE) inhibitors or angiotensin II receptor blockers (ARBs) by patients with particular conditions, including diabetes, heart failure, and proteinuria.
- Use of beta blockers following discharge for acute myocardial infarction.
- Use of tamoxifen or an aromatase inhibitor in patients with Stage IC through IIIC estrogen receptor (ER) or progesterone receptor (PR) positive breast cancer.

Two such measures are listed in the supplemental measures on the CMS website, but only are applied to MA plans because of the need for diagnosis information that PDPs may not have. Both are measures of persistence of use after six months: one for antidepressant medications, and one for beta blockers after a heart attack. The challenge in using any of these measures for Part D is that they rely on knowing a beneficiary's diagnosis. In some cases, this information may already be compiled in the risk adjustment information associated with each beneficiary. For example, the RXHCC system has two HCC groups for patients with diabetes, and one for congestive heart failure. Alternatively, some measures consider the use of a drug that treats diabetes as a proxy for diabetes.

In other cases, getting to the level of detail required might be possible by linking Part D claims with Part A/B claims, such as looking for hospital stays associated with acute myocardial infarction. But some measures are likely too specific to be used with the available data, even in A/B claims. For example, ICD-9 and ICD-10 diagnosis codes for breast cancer identify the location of the cancer, but not the stage or whether it is ER or PR positive.

These individual drug measures could be of use in plan oversight, looking for problems that might stem from plan behavior or formulary design. For beneficiaries choosing among their plan options, measures of adherence related to individual conditions are far too specific, but an aggregate of several of these measures might be a useful tool for judging whether plan enrollees are able to fill prescriptions for drugs in specific situations when they are widely accepted as clinically desirable.

Beneficiary Survey Questions on Access to Drugs

CAHPS surveys beneficiaries on several issues related to satisfaction with prescription drug plans, including these questions that could be linked to access to drugs:¹⁰

- In the last 6 months, did a doctor prescribe a medicine for you that [PLAN] did not cover?
- When this happened, did you contact [PLAN] to ask them to cover the medicine your doctor prescribed?
- When you contacted [PLAN] about the decision not to cover a prescription medicine did they:
 - Tell you that you can file an appeal
 - Offer to send you forms that you need to file an appeal
 - Suggest how to resolve your complaint
 - Listen to your complaint but did not help to resolve it
 - Discourage you from taking action
 - Do none of these things
- In the last 6 months, how often was it easy to use [PLAN] to get the medicines your doctor prescribed?
- In the last 6 months, how often was it easy to use [PLAN] to fill a prescription at a local pharmacy?
- In the last 6 months, how often was it easy to use [PLAN] to fill a prescription by mail?
- Using any number from 0 to 10, where 0 is the worst prescription drug plan possible and 10 is the best prescription drug plan possible, what number would you use to rate [PLAN] for coverage of prescription drugs?
- In the last 6 months, did you ever delay or not fill a prescription because you felt that you could not afford it?

In shopping for plans, beneficiaries likely will not want to synthesize the answers to all eight of these questions. Further research could be done on how the answers to these questions are correlated with each other and with other measures of access described in this report, to either come up with a composite score on access or one or two representative questions. Meanwhile, CMS may want to continue to monitor individual questions to target specific problems with plans.

Availability of Pharmacies and 90-Day Supplies

One issue of concern as Part D was being established was whether Part D sponsors would seek to contract only with a limited number of pharmacies. The MMA required plan sponsors to secure access to a sufficient number of pharmacies (other than mail order) to ensure convenient access (including adequate emergency access). Part D regulations specify that a Part D plan must have a contracted pharmacy network, other than mail-order pharmacies,

¹⁰ The full proposed questionnaire for the 2011 CAHPS is included as Appendix C to this report.

consisting of retail pharmacies sufficient to ensure that for enrollees residing in the plan's service, the following requirements are met:

- Urban areas: at least 90% of enrollees, on average, live within 2 miles of a network pharmacy;
- Suburban areas: at least 90% of enrollees, on average live within 5 miles of a network pharmacy; and
- Rural areas: at least 70% of enrollees, on average, live within 15 miles of a network pharmacy.

To monitor compliance with these rules, CMS requires plans to report on the percentage of beneficiaries living within the relevant radius of a pharmacy for each of these categories.

Plans also must report on the contracted pharmacies in their service areas. On the Plan Finder, CMS currently offers beneficiaries the option to see which pharmacies within a small radius of a zip code are included in the plan's network. In a review of the plans for three zip codes in different parts of the country, we found small differences among plans in the number of pharmacies listed (Table 2). It seems that either measure of pharmacy access (beneficiaries within a certain distance of a pharmacy, and the number of pharmacies in network) would be useful in describing differences among plans in the abstract. However, for beneficiaries who have a specific pharmacy that they prefer, the current Plan Finder system of showing the list of actual pharmacies that are in a plan's network may be the most meaningful way to communicate the relevant information.

Table 2. Number of Pharmacies Listed In Network, For All Plans in Three Zip Codes

Number of Pharmacies Listed In Network	Number of Plans		
	Zip code 20814	Zip code 94110	Zip code 67212
6			5
7		3	40
8	3	2	
9	35	41	
10	7		

SOURCE: NORC/Georgetown/SSS analysis of CMS Plan Finder website, <http://www.medicare.gov/find-a-plan/questions/home.aspx>.

Plans are also required to report on how many of the retail pharmacies in their network are authorized to provide 90-day supplies of medications. This may be important to some beneficiaries who are wary of using mail-order pharmacies. We are not aware of whether this is a measure that varies significantly from plan to plan.

Measures of Timeliness in Filling Prescriptions

Part D plans could be considered accountable for two aspects of the time that it takes to fill prescriptions. First, to the extent that they have a mail order pharmacy to which they steer beneficiaries, they are responsible for all prescriptions filled by that mail order pharmacy. URAC includes several measures related to the timeliness of mail order pharmacy in its PBM accreditation review: turnaround time for clean prescriptions, turnaround time for prescriptions requiring intervention, and an overall measure of turnaround time.

Second, to the extent that plan policies related to prior authorization, step therapy, or restrictive formularies slow down turnaround time at all pharmacies, differences among plans in retail turnaround time could provide some meaningful information for plan oversight. To make the measure more meaningful, an analysis could control for the average turnaround time of the pharmacy filling the prescription before comparing plans across all pharmacies.

It does not appear that plans are required to submit information about turnaround time (mail order or retail) with claims data or in the quarterly reports that plans submit to CMS. E-prescribing data might be another source of data on turnaround time for a subset of beneficiaries.

Measuring Quality and Safety of Care

Quality of care is perhaps the most difficult aspect of plan performance to measure objectively. However, there are many quality measures that have been developed by organizations dedicated to that task, including the adherence measures included in the previous section. In this section, we also explore measures of whether plans are allowing access to certain drugs that are considered high-risk for the elderly; utilization management aimed at improving quality and safety; monitoring drug-drug interactions; grievances filed for quality of care; and medication therapy management.

Utilization of High-Risk and Highly-Recommended Drugs

In the section on adherence above, we discussed the concept that plans could be judged on access simply by measuring how many prescriptions their enrollees fill. However, not all use is necessarily good. One way around this, as we discussed, is to look specifically at utilization for drugs that are widely considered to be recommended for a particular category of enrollees, such as those with diabetes. For example, one of the measures currently incorporated in the summary measures shown on the Drug Plan Finder is whether beneficiaries are using the kind of blood pressure medication that is recommended for people with diabetes. CMS bases this measure on a PQA measure and recently updated the list of drugs considered. Such measures could be considered a measure of plan quality as well as one of access.

At the same time, there are certain categories of drugs that are considered to impose high risks for the elderly. One commonly cited list of such drugs is the Beers list, which was developed by a consensus process with experts in geriatric care and pharmacology, and has been shown to accurately predict adverse drug events among the elderly.^{11,12} Researchers in Canada developed a similar, but shorter, list of high-risk drugs called the Improving Prescribing in the Elderly Tool,¹³ and researchers in Europe have developed a list called the Screening Tool for Older People's Potentially Inappropriate Prescriptions (STOPP).¹⁴ All three lists are included in Appendix D. However, these lists can be controversial. Clinicians may still have good reasons to prescribe these drugs at times for specific elderly patients. Furthermore, at least one study has found that Beers list drugs are not the most common cause of adverse events; drugs like warfarin, insulin, and digoxin cause more emergency department visits.¹⁵

One aspect of all of these lists is that many contraindications are disease-specific. For example, NSAIDs are contraindicated for patients with hypertension, but not necessarily for other elderly patients. Thus, many of the checks implied by these lists would require a Part D plan to have diagnosis information about a beneficiary. However, all lists – and particularly the Beers list – include some drugs that are generally contraindicated for all elderly patients.

CMS uses an NCQA measure of utilization of High-Risk Medications in the Elderly, based on the Beers list, as part of its star ratings for plans. This NCQA list is also included in Appendix D. In July 2010, CMS announced it would use an updated list of drugs specified by PQA for its measure. Both NQF and PQA have also endorsed two measures of utilization of these contraindicated drugs: the percentage of enrollees over age 65 who received at least one drug to be avoided, and the percentage who received at least two different drugs to be avoided in the elderly.

Other potential measures related to these contraindicated drugs might come from a Part D plan's formulary. For example, CMS could review coverage, tier placement, and utilization management of these drugs, encouraging plans to make it more difficult for beneficiaries to

¹¹ Fick DM, Cooper JW, Wade WE, Waller JL, Maclean JR, Beers MH. "Updating the Beers criteria for potentially inappropriate medication use in older adults: results of a US consensus panel of experts." *Archives of Internal Medicine* 163 (2003):2716-2724.

¹² Lund BC, Carnahan RM, Egge JA, Chrischilles EA, Kaboli PJ. "Inappropriate prescribing predicts adverse drug events in older adults." *Annals of Pharmacotherapy* vol. 44 no. 6 (2010):957-63.

¹³ Christopher T Naugler, Chris Brymer, Paul Stolee, Zora Arcese. "Development and validation of an Improving Prescribing in the Elderly Tool." *Canadian Journal of Clinical Pharmacology* Vol. 7, No. 2 (2000): 103-107.

¹⁴ Gallagher P, O'Mahony D."STOPP (Screening Tool of Older Persons' potentially inappropriate Prescriptions): application to acutely ill elderly patients and comparison with Beers' criteria." *Age and Ageing* vol. 37 no. 6 (2008):673-9.

¹⁵ Budnitz et al., "Medication Use Leading to Emergency Department Visits for Adverse Drug Events in Older Adults." *Annals of Internal Medicine* 147 (2007): 755–765.

receive drugs that are contraindicated for the elderly. To explore this possibility, we did some empirical tests on the list of drugs to be avoided in the elderly that CMS uses for its published performance measure. Specifically, we identified whether these potentially high-risk drugs are on formularies, and if so, whether plans place restrictions on them (Table 3). Compared to all other drugs, these high-risk drugs are modestly less likely to be on formulary, but also slightly more likely to require prior authorization. When they do appear on a plan’s formulary, these drugs are equally likely to be on a generic or preferred brand tier, compared to other non-specialty drugs.

Table 3. Formulary Status and Utilization Management for Potentially High-Risk Drugs for the Elderly

	% off formulary	% generic or preferred tier, if listed	% PA if listed	% ST if listed	% QL if listed
Potentially high-risk drugs	25%	64%	13%	3%	15%
Other non-specialty drugs (on specialty tier <10%)	14%	63%	7%	5%	22%

SOURCE: NORC/Georgetown/SSS analysis of plan formulary files. Further information about NORC/Georgetown/SSS analysis of plan formularies is available in *Medicare Part D Formularies, 2006-2010: A Chartbook*, at www.medpac.gov.

We also performed a plan-level analysis using this set of high-risk drugs (Table 4). Formulary listing does not seem particularly predictive of the CMS utilization of drugs to be avoided in the elderly in the aggregate. However, there does seem to be a possible association between prior authorization requirements for these drugs and a reduction in their use. Of the nine plans with the highest levels of PA for these drugs, eight achieved better-than-median ratings (lower use of these drugs). The plan sponsor with the least utilization of potentially higher-risk drugs applies prior authorization to 83% of these drugs when it lists them on formulary – a level nearly four times that of the PA use for the next plan sponsor. And the plan that is second on use of PA also has the second best rating on limiting utilization of these drugs.

Table 4. Utilization of High-Risk Drugs for the Elderly in National Plans, by Plans' Relative Amount of Restrictions on Those Drugs

	Number of National Plans	
	Worse than median rating on use of high-risk drugs (higher use)	Better than median rating on use of high-risk drugs (lower use)
Listing high-risk drugs on formulary at about the same rate as other drugs	13	14
Listing high-risk drugs on formulary less often than other drugs	9	8
Using PA for under 20% of high-risk drugs on-formulary	21	14
Using PA for 20% or more of high-risk drugs on-formulary	1	8

SOURCE: NORC/Georgetown/SSS analysis of plan ratings for 2010 and 2010 plan formulary files. Plan ratings are available on CMS Plan Finder website, <http://www.medicare.gov/find-a-plan/questions/home.aspx>. Further information about NORC/Georgetown/SSS analysis of plan formularies is available in *Medicare Part D Formularies, 2006-2010: A Chartbook*, at www.medpac.gov.

Drug-Drug Interactions and Other Adverse Drug Events

The lists described in the previous section include some classes of potential drug-drug interactions, but there are many other potential interactions. Both Part D plans and pharmacies should have checks within their computer systems to compare a new prescription with a beneficiary's recent prescriptions to flag any potential interactions, although there is some evidence that pharmacists frequently override these flags.¹⁶

CMS has also recently introduced two new measures that are part of the Part D display measures on the CMS website, but not currently used for the Plan Finder. CMS also makes available to plan sponsors monthly patient safety reports based on these measures to allow sponsors to compare their status to overall averages and to monitor improvements over time.¹⁷

¹⁶ Jacob Abarca et al. "Community Pharmacy Managers' Perception of Computerized Drug-Drug Interaction Alerts." *Journal of the American Pharmacists Association* 2006 ; 46(2):148-153.

¹⁷ Memo to Part D Sponsors from Cynthia Tudor, CMS, July 16, 2010.

One measure addresses drug-drug interactions, based on how many of the patients receiving a drug on a target list of medications also were dispensed a medication contraindicated for use with the target medication (at the same time or subsequent to the initial prescription). The other addresses how often patients were dispensed a dose higher than the daily recommended dose for certain diabetes drugs. As with individual drugs that are considered high-risk, there may be cases in which prescribing a combination of drugs that can be potentially harmful is still the best available treatment option for a patient. However, the goal of these measures is to minimize the use of these potentially dangerous combinations.

Another option would be to monitor Part A and B claims for physician visits and hospital visits for what appear to be adverse drug events. For example, Gurwitz et al. identified diagnoses and treatments that appear to be related to drug-related incidents, including ICD-9 codes for poisoning by a variety of agents, and the use of antidotes.¹⁸ (With electronic medical records, lab results for certain serum drug levels were also available in their study.)

Utilization Management Related to Quality of Care

Another method for preventing beneficiaries from using drugs that are unsafe for a particular situation is to require prior authorization. This is another area in which monitoring of plan formularies could become more refined. In theory it might be possible to distinguish between prior authorization requirements that are likely to be confirming that a physician truly believes that a potentially dangerous drug is the best option for his or her patient, and other prior authorization requirements that appear to be related more purely to costs. For example, if the overall level of prior authorization restrictions is used as a descriptor of plan formularies, it might be appropriate to exclude or discount the prior authorization requirements for drugs that are considered high-risk for the elderly, while giving more weight to prior authorization requests for drugs that do not have any such concerns. But creating such a list is likely to be challenging.

Similarly, plans appear to commonly use quantity limits to prevent beneficiaries from filling a prescription for more than 30 days of some expensive drugs. In some cases, however, quantity limits are more specifically targeted to ensure that beneficiaries do not take an unsafe amount of the drug. A sophisticated system for describing plans might differentiate between these two kinds of quantity limits.

¹⁸ Jerry Gurwitz et al. "Incidence and Preventability of Adverse Drug Events Among Older Persons in the Ambulatory Setting." *Journal of the American Medical Association* Vol. 289, No. 9 (2003): 1107-1116.

Grievances Related to Quality of Care

CMS lists the number of grievances filed related to quality of care as one of its plan measures. It is not entirely clear what this would include, and information is not publicly available.

Medication Therapy Management

All Part D plans are required to have medication therapy management programs, but more work could be done to create measures of the effectiveness of these interventions. For 2010, CMS has instituted new guidelines for these programs, requiring sponsors to provide an annual, person-to-person review of medications for targeted beneficiaries. Programs must target at least four of seven core chronic conditions: hypertension, heart failure, diabetes, dyslipidemia, respiratory diseases, bone disease and arthritis, and mental health.

There are quality measures in use outside of Part D that might also be relevant here. For example, the NCQA recommends measures of whether patients aged 65 and older who have a hospital stay have their medications reviewed by a physician to reconcile any new prescriptions with their previous medication list. While MTM programs are currently targeted at beneficiaries who take a large number of drugs, recently hospitalized beneficiaries could be another population that would benefit from this service.

Measuring Cost

Plan premiums are one obvious measure of plan cost that both beneficiaries and CMS can use to compare plans. Under the rules of plan bidding and actuarial equivalence, the effects of other elements of plan costs should show up in plan premiums. But much more could be understood about how plans perform on individual measures that should be contributing to overall costs, including price increases; generic dispensing; overall spending; out-of-pocket costs; and rebates.

Accuracy of Prices in the Plan Finder, and Increases During the Year

One complaint about plans in the first few years of Part D was that Plan Finder prices could be quite different from what beneficiaries paid at the pharmacy. A July 2009 report by the HHS Office of the Inspector General (OIG) considered whether drug prices displayed on the Drug Plan Finder accurately reflect actual drug costs on Part D claims.¹⁹ OIG found that the prices on Plan Finder generally exceeded actual drug costs, frequently by large amounts. Plan Finder

¹⁹ Office of the Inspector General, Department of Health and Human Services, "Accuracy of Part D Plans' Drug Prices on the Medicare Prescription Drug Plan Finder," July 2009, OEI-03-07-00600. Accessed at <http://oig.hhs.gov/oei/reports/oei-03-07-00600.pdf>

prices were 28 percent (or \$18) higher than actual drug costs at the median for the 10 drugs included in the review.

CMS now uses the accuracy of Plan Finder prices as a performance measure. Any deviation of more than 5 percent between the Plan Finder price and the price shown in drug claims is counted against the plan, in a measure that is weighted by the volume of prescriptions. This is one of the five measures included in the star rating for the “pricing and patient safety” domain on the Plan Finder. In the supplemental measures on the CMS website, CMS is also tracking the share of each plan's prices that result in suppression on the Plan Finder because they do not pass CMS's quality assurance checks.²⁰

The other price-related measure that CMS includes in the “pricing and patient safety” domain is whether prices increase “more than expected” during the year. This is calculated as the volume-weighted share of drugs that increased by more than 5 percent more than twice during any given time period.

While these two measures may be of interest to beneficiaries, they seem more useful as a check on how much to trust a plan's price information – almost as much a measure about the plan's administration as about prices. These measures may give beneficiaries a sense of how much weight to give price information as a factor in their decision, but they do not provide a meaningful way to compare plans on the actual prices they offer. The remaining measures that we suggest below offer some ways that beneficiaries and CMS might better compare plans on the basis of cost.

Generic Dispensing Rate

The generic dispensing rate could be an important measure not only of plan management and cost control, but also of beneficiary out-of-pocket costs. To the extent that beneficiaries are being steered to generics with lower cost sharing, their overall costs should be lower. The lower patient cost sharing typically available for generics has also been shown to increase adherence to medications, possibly improving health along with those savings.²¹

CMS monitors generic dispensing as a simple ratio of claims for generic drugs to claims for all drugs. The generic dispensing rate for Part D grew steadily over the first three years of the

²⁰ For a description of these checks, see Cynthia Tudor, “Quality Assurance Checks for 2010 Data Submitted for Posting on the Medicare Prescription Drug Plan Finder Tool.” Memo to All Part D Sponsors, July 1, 2009. http://www.cms.gov/PrescriptionDrugCovContra/Downloads/MemoPFQAChecks_07.01.09.pdf

²¹ Michael Chernew et al., “Impact of Decreasing Copayments on Medication Adherence Within a Disease Management Environment,” *Health Affairs* 27(1):103-112, January/February 2008; Sebastian Schneeweiss et al., “Adherence to Statin Therapy Under Drug Cost Sharing in Patients With and Without Acute Myocardial Infarction: A Population-Based Natural Experiment,” *Circulation* 115(16): 2128-2135, April 24, 2007.

program, reaching nearly 70 percent in 2008. Rates varied somewhat by plan, with Medicare Advantage (MA) plans dispensing generics at a rate of 72 percent in 2008 compared to 66 percent for PDPs. Individual PDPs varied from 54 percent to 76 percent.²²

Other more nuanced measures of generic utilization would control for the fact that generics are not available for every drug. This might include measuring the share of generic use for chemical entities with generics available, and the share of generic use within drug classes that have a generic available in the class. MedPAC has also shown that it can be helpful to look at particular drug classes and particular populations when considering the generic dispensing rate. For example, for diabetes drugs, there is a notable difference in the generic dispensing rate between low-income subsidy (LIS) and non-LIS populations (53 percent vs. 65 percent).²³

These claims-based measures of generic dispensing could give both beneficiaries and CMS meaningful information on individual plans' past performance. Research is needed to understand more about the relationship between generic dispensing rates and plan design – which might enable beneficiaries to choose plans prospectively, and might enable plans to create more effective formulary designs. HCFO recently funded our research team to explore this issue further through analysis of Part D prescription drug claims.

Total Spending on Medications

The generic dispensing rate is in some respects a proxy for a plan's success in steering beneficiaries to lower cost drugs. Another approach would be to measure beneficiary spending more directly. This could be done on a risk-adjusted, per-member month basis, or a measure could look at spending per prescription. (One limitation in using Part D claims for this purpose is the inability to look at drugs obtained outside the Part D benefit.) Just as the generic dispensing rate may vary from plan to plan, some plans may be more effective than others in steering beneficiaries to lower-cost drugs, whether those drugs are generics or lower-cost brands.

MedPAC recently published an analysis of drug price increases across all of Part D. While overall prices rose by an average of 11 percent over the first two years of the program, a price index that took generic substitution into account actually declined by 3 percent over the same period.²⁴ A similar analysis might be possible on a plan-by-plan basis. This would require looking retrospectively at claims, but again, research could test whether certain plan designs

²² Michelle Ketcham and Luping Qu, "Part D Drug Utilization and Cost Trends." Presentation at the CMS Part D Symposium, March 18, 2010.

²³ Shinobu Suzuki. "MedPAC analysis of Factors Affecting LIS Use of Prescription Drugs." Presentation at the CMS Part D Symposium, March 18, 2010.

²⁴ MedPAC, "Status Report on Part D." in *Report to the Congress: Medicare Payment Policy*. March 2010.

are associated with a greater success in substituting lower-cost drugs and lowering total spending.

Out-of-Pocket Costs and Negotiated Prices for Medications

The Medicare Plan Finder is extremely valuable to beneficiaries who want to compare plans on the basis of coverage of and out-of-pocket costs for the medications they are already taking. It does not attempt, however, to compare plans on the potential costs beneficiaries might face if they are prescribed different drugs in the future.

Overall, plans are required to set their cost sharing equal to 25 percent of drug costs, averaged across beneficiaries. But they may get to that amount by setting cost sharing amounts that are effectively higher or lower than 25 percent for certain types of drugs, having different effects on beneficiaries with different conditions. The cost sharing arrangements used by plans can be difficult even for experts to compare across plans – particularly when comparing tiered flat-dollar copayments to cost sharing that is set as a percentage of the retail price of a drug. One possible comparison tool would be an estimate of the expected out-of-pocket costs for a given market basket of drugs – or for several scenarios of medication use. This might enable beneficiaries to make a more meaningful comparison among plans' different cost sharing structures.

Retail prices paid by plan enrollees may vary from plan to plan because of negotiated retail discounts and varying dispensing fees. Because retail prices do not include rebates from manufacturers, they do not capture the full range of variation in the ultimate prices paid by plan sponsors. Nevertheless, information on differences among plans in their average negotiated retail prices could be another way for beneficiaries to compare costs across plans.

Rebates

Rebates do not affect retail prices for beneficiaries, but they can affect both the government's and the beneficiary's cost for premiums and possibly cost sharing. It is not clear whether the size of rebates is important on its own, separate from these aspects of plan costs. CMS requires plan sponsors to report on the value of rebates, pending rebates, and prior rebates, by drug name. Sponsors also must report on other price concessions that they receive from manufacturers, allocated among each of their plans.²⁵ These data are not publicly available, due to the proprietary nature of the agreements between plan sponsors and manufactures. Sponsors and manufacturers argue that prices might rise if sponsors had to disclose the rebates they receive. However, it might be possible for CMS to report on aggregate measures at the

²⁵ CMS, "Final Medicare Part D DIR Reporting Requirements for 2009 Payment Reconciliation." Memo to All Part D Plan Sponsors, June 10, 2010.

plan level, to compare the effectiveness of different plans in obtaining price concessions. For monitoring the Part D market, such information might be particularly interesting in combination with information on plans' formulary design, because decisions about coverage, tier placement, and utilization management are often made in conjunction with negotiations over rebates. However, rebates would be much less relevant than other price information for beneficiaries making enrollment decisions.

Measuring Customer Service and Program Administration

If a plan has poor customer service or poor administration, the effects will likely be seen across the board on other measures we describe in this report – decreasing access to drugs, threatening the quality of care, and not controlling costs. However, there are many measures that also describe the “hassle factor” of a plan, independent of whether the effects of that hassle spill over into other domains. Three of the four Plan Finder star rating domains include components that we would put in this category, including five of the seven measures in its star rating for “customer service,” all four under “member complaints”, and one of the three under “member experience.” In fact, these measures make up the majority of measures in the Plan Finder star ratings (see Appendix A). We discuss the measures here, and some considerations and possible expansions on how to think about customer service and program administration. We have organized them into different categories from the CMS domains, including information for beneficiaries, pharmacists, and providers; complaints by beneficiaries, pharmacists, and providers; and problems uncovered in CMS audits and fraud and abuse reports.

Information for Beneficiaries

As Part D rolled out, it quickly became clear that many plans had not anticipated the volume of calls they would receive from beneficiaries. There were numerous reports of long wait times and dropped calls. HHS began monitoring plans' customer service call centers in 2006, and CMS continues this work four years later. Three measures stemming from this work are included in the star rating for “drug plan customer service” on the Plan Finder:

- Time on hold when customer calls drug plan;
- Accuracy of information members get when they call the drug plan; and
- Availability of TTY/TDD services and foreign language interpretation when members call the drug plan.

In the supplemental measures on the CMS website, CMS is also tracking how often calls are disconnected when a customer calls the drug plan, the number of calls that are answered within 30 seconds, and the understandability of the plan's customer service representatives. This cluster of issues seems important for monitoring. CMS has set standards that they expect

all plans to meet on the measures currently included in the star ratings, such as an average 2 minute wait time on the phone. Because of these basic standards, however, these measures seem less important as a factor for beneficiaries to consider when enrolling in a plan. Ideally, beneficiaries would be able to trust that CMS is requiring plans to offer quick, accurate answers, without trying to factor this into their plan choice.

Additional measures on this topic are available from CAHPS. The survey includes the following module on whether beneficiaries got the information they needed from their plan:

- In the last 6 months, how often did [PLAN]'s customer service give you the information or help you needed about prescription drugs?
- In the last 6 months, how often did [PLAN]'s customer service staff treat you with courtesy and respect when you tried to get information or help about prescription drugs?
- In the last 6 months, how often did [PLAN] give you all the information you needed about which prescription medicines were covered?
- In the last 6 months, how often did [PLAN] give you all the information you needed about how much you would have to pay for your prescription medicine?

The first question is one of three measures incorporated into the star rating for the “member experience” domain on the Plan Finder. This more subjective measure of whether plans provide the information beneficiaries need is harder to use as a performance standard, and probably does make sense as part of a rating system that beneficiaries can use to compare plans.

Information for Providers and Pharmacists

The star rating for the “drug plan customer service” domain also includes two measures that consider the availability of information for pharmacists who are serving a plan’s enrollees. The first is the time on hold when pharmacist calls drug plan, measured by CMS calls to customer service call centers. In supplemental measures, CMS is also tracking how many calls are disconnected when pharmacists call the drug plan.

The second measure included in the current star ratings is generated from administrative data to measure how often the drug plan provides pharmacists with up-to-date and complete enrollment information about plan members. The star ratings include a measure of how often plans are able to process CMS-generated enrollments in the expected time period; a supplemental measure on the CMS website also looks at how often plans send CMS the needed information for plan-generated enrollments in a timely manner. Like several of the measures related to beneficiary information, these measures of call center performance and enrollment processing seem to be performance standards that could be a basic requirement for plans and a basis for CMS oversight, rather than a measure that beneficiaries use to compare plans.

Another important measure of plan performance is the completeness of the plan's information about whether beneficiaries are enrolled in the low-income subsidy program. This is not only a sign of good plan administration, but it can have important cost and access implications for beneficiaries.

It might also be helpful to know how providers feel about the information that is available from plans. In particular, if providers want to help beneficiaries use their plan's formulary most effectively, they need good information about what is covered, on what tier, and with what other requirements. We are not aware of a source of information that would provide information by plan on whether providers feel that they have this information. One test that might be of increasing importance over time would be to check the accuracy and timeliness of the information that is available in various electronic prescribing systems. Providers could also be a valuable information source regarding such things as the responsiveness of plans or the clinical appropriateness of UM requirements.

Complaints by Beneficiaries

CMS includes two measures specifically about complaints filed by beneficiaries in the star ratings for the "member complaints" domain. One has to do with complaints about enrollment and disenrollment. CMS lists a number of subcategories that might be included in this measure, including: delayed enrollment or disenrollment processing, not receiving Part D card or enrollment materials, inappropriate enrollment or disenrollment, enrollments denied inappropriately, difficulty switching between plans, problems with Low Income Subsidy (LIS) enrollment, or inconsistent enrollment practices in the same state.

The other measure includes all other beneficiary complaints to CMS about any other issues with a plan. It is likely that the number of beneficiaries who make formal complaints to Medicare about their plans is only a small fraction of the beneficiaries who have some sort of complaint. There is no reason to assume that these beneficiaries are unevenly distributed across plans, unless some plans are better than others about telling beneficiaries that they can make a complaint to CMS, and how to do so. It is important thus that plans with a higher complaint rate are not penalized if it results from providing better information to beneficiaries.

A third measure related to complaints is included in the supplemental measures on the CMS website. This measure seeks to track how many complaints are closed out by the plan before they are truly resolved, or without following best practices for complaint resolution.

Complaints by Pharmacists and Providers

CMS has a system available for pharmacists and physicians to make complaints about Part D plans. While these complaints are available for plan monitoring, they do not currently make up

a part of the rating system for beneficiaries. It is likely that most provider complaints will be access-related; such a measure might make sense in combination with other access-related measures.

Another potential source of dissatisfaction with Part D plans is the speed with which they pay pharmacies. This is an area that is monitored by CMS, but not currently a source of public plan ratings. It makes sense that this would be an area in which CMS can require certain performance standards, without beneficiaries worrying about comparing plans on this metric.

Audit Problems and Potential Fraud and Abuse

The final measure in the “member complaints” domain is derived from audits that CMS does of Part D plans. CMS categorizes the findings of each audit in terms of the potential harm to beneficiaries, either financially or in terms of access to medications. Plan ratings are derived from the points assigned in the audits.

In addition, CMS requires plans to report on “potential fraud and abuse” at the contract level. This includes incidents related to billing, false information, drug seeking, identity theft, and other areas. Plans are supposed to report on the number of incidents reported to authorities and the corrective actions taken. This information seems difficult to interpret. It seems unlikely that plans will self-report any serious fraud or abuse they are trying to perpetrate; if they are reporting attempted fraud or abuse by others, it seems that more reports might be a sign of better plan oversight on this measure. Thus, it is probably reasonable that this information is not included in the plan rating system.

Measuring Overall Plan Satisfaction

There are also some ways that overall satisfaction with Part D plans can be measured, beyond the four domains we have described above. These measures include self-reported satisfaction and disenrollment from plans.

Self-Reported Satisfaction

CAHPS asks two questions that aim to assess enrollees’ overall satisfaction with a plan:

- Using any number from 0 to 10, where 0 is the worst prescription drug plan possible and 10 is the best prescription drug plan possible, what number would you use to rate [PLAN] for coverage of prescription drugs?
- Would you recommend [PLAN] for coverage of prescription drugs to other people like yourself?

The ten-point rating of the drug plan is one of three questions (along with the plan providing information when members need it, and the ability to fill prescriptions easily) that feeds into a star rating for the “member experience” domain on the Plan Finder. Beneficiaries might find the information more meaningful if the overall satisfaction questions were treated separately, because they provide an overarching view of what other beneficiaries think of each plan.

Disenrollments

Disenrollments may be seen as the ultimate measure of dissatisfaction. Through the Part D enrollment system, CMS tracks how many beneficiaries voluntarily disenroll from a plan. This measure is also part of the star rating for the “member complaints” domain. Disenrollment is seemingly an objective measure, but there may be many different reasons for disenrollment, and some may be more serious than others. For example, if a beneficiary is switching plans because he or she believes another plan offers better coverage for a specific drug, that decision may not be one that has relevance to other beneficiaries that do not take that drug. If beneficiaries were asked to report their reason for disenrollment, this might provide an important tool for making sense of disenrollment data.

Appendix A. CMS Part D Performance Measures

In this appendix, we have included measures currently displayed to beneficiaries in the Plan Finder, as well as a second set of measures that CMS has posted on the medicare.gov website.

Measures Used for Star Ratings on the Plan Finder

Drug Plan Customer Service

- Time on hold when customer calls drug plan
- Time on hold when pharmacist calls drug plan
- Accuracy of information members get when they call the drug plan
- Availability of TTY/TDD services and foreign language interpretation when members call the drug plan
- Drug plan's timeliness in giving a decision for members who make an appeal
- Fairness of drug plan's denials to a member's appeal, based on an independent reviewer
- Drug plan provides pharmacists with up-to-date and complete enrollment information about plan members

Member Complaints, Members Who Choose to Leave, and Medicare Audit Findings

- Complaints about joining and leaving the drug plan
- All other complaints about the drug plan
- Members choosing to leave the drug plan
- Seriousness of problems Medicare found during an audit of the drug plan

Member Experience With Drug Plan

- Drug plan provides information or help when members need it
- Members' overall rating of drug plan
- Members' ability to get prescriptions filled easily when using the drug plan

Drug Pricing and Patient Safety

- Completeness of the drug plan's information on members who need extra help
- Drug plan prices that do not increase more than expected during the year
- Drug plan prices on Medicare's website are similar to the prices members pay at the pharmacy
- Drug plan members 65 or older who receive prescriptions for certain drugs with a high risk of side effects, when there may be safer drug choices
- Using the kind of blood pressure medication that is recommended for people with diabetes

SOURCE: CMS, "CY2010 Medicare Part D plan Ratings Technical Notes." February 2010.
<http://www.cms.gov/PrescriptionDrugCovGenIn/Downloads/PartDMedicarePlanRatings.zip>

Supplemental Measures on the CMS Website

Access

- Timely receipt of case files for appeals, when requested by IRE
- Timely effectuation of appeals decisions
- Timely enrollment processing

Call Center

- Calls disconnected when customer calls drug plan
- Calls disconnected when pharmacist calls drug plan
- CSR understandability
- Call answer timeliness (percent within 30 seconds)

Complaints

- Appropriate complaint resolution

Patient Safety

- Drug-drug interactions
- Diabetes medication dosing

Plan Finder

- Drug plan provides current information on costs and coverage for Medicare's website

Medicare Advantage Plan Measures Related to Prescription Drug Use

- Follow-up visit after hospital stay for mental illness (within 30 days of discharge)
- Antidepressant medication management (patients remain on medication for 6 months)
- Continuous beta blocker treatment (patients with MI remained on beta-blockers for 6 months after discharge)

SOURCE: CMS, "Part D Medicare Plan Ratings Display Measures (v03.30.10)." Accessed at http://www.cms.gov/PrescriptionDrugCovGenIn/06_PerformanceData.asp

Appendix B. Recommended Drugs and Measures of Adherence

The following are measures specific to medication adherence, compiled from URAC, the National Quality Foundation (NQF), the Centers for Medicare & Medicaid Services (CMS), the Pharmacy Quality Alliance (PQA), and AHRQ's National Quality Measures Clearinghouse (NQMC), which includes measures from such organizations as the American Medical Association (AMA), the National Committee for Quality Assurance (NCQA), and other organizations. This list does not include measures related to over the counter medications or vaccines, or measures primarily oriented toward a pediatric population.

All drugs

- **Medication Possession Ratios for Mail Service (URAC):**
 - Part A: Medication Possession Ratios for New Users
 - Part B: Medication Possession Ratios for Continuing Users
 - Part C: Overall Medication Possession Ratios (New and Continuing Users Combined)
- **Adherence to Chronic Medications (NQF):** Medication Possession Ratio (MPR) for chronic medications for individuals over 18 years of age
- **Medication Possession Ratios for Specialty Pharmacy (URAC):**
 - Part A: Medication Possession Ratios for New Users
 - Part B: Medication Possession Ratios for Continuing Users
 - Part C: Overall Medication Possession Ratios (New and Continuing Users Combined)
- **Outpatient drug utilization (NQMC/NCQA):** summary of outpatient utilization of drug prescriptions, stratified by age, during the measurement year.
 - total cost of prescriptions
 - average cost per member per year
 - total number of prescriptions
 - average number PMPY

Cancer

- **Prostate Cancer: Adjuvant Hormonal Therapy for High-Risk Patients (NQMC/AMA/NQF):** Percentage of patients with a diagnosis of prostate cancer, at high risk of recurrence, receiving external beam radiotherapy to the prostate who were prescribed adjuvant hormonal therapy (GnRH agonist or antagonist)
- **Adjuvant hormonal therapy for breast cancer**
 - NQF: Percentage of female patients, age >18 at diagnosis, who have their first diagnosis of breast cancer (epithelial malignancy), at AJCC stage I, II, or III, who's primary tumor is progesterone or estrogen receptor positive recommended for tamoxifen or third generation aromatase inhibitor (considered or administered) within 1 year (365 days) of diagnosis
 - NQMC/AMA /NQF: Percentage of female patients aged 18 years and older with Stage IC through IIIC, estrogen receptor (ER) or progesterone receptor (PR) positive breast cancer who were prescribed tamoxifen or aromatase inhibitor (AI) within the 12 month reporting period

- NQMC/ASCO: percentage of patients for whom tamoxifen or third generation aromatase inhibitor is considered or administered within 1 year (365 days) of diagnosis for women with AJCC T1c or stage II or III hormone receptor positive breast cancer.

Hematology

- **Multiple Myeloma - Treatment with Bisphosphonates** (NQMC/AMA /NQF): Percentage of patients aged 18 years and older with a diagnosis of multiple myeloma, not in remission, who were prescribed or received intravenous bisphosphonates within the 12 month reporting period
- **Myelodysplastic syndrome** (NQMC/AMA): percentage of patients aged 18 years and older with a diagnosis of myelodysplastic syndrome (MDS) who are receiving erythropoietin therapy with documentation of iron stores prior to initiating erythropoietin therapy.

Cardiovascular - ACEI/ARB

- **Proportion of Days Covered**
 - PQA: The percentage of patients who were dispensed either an angiotensin-converting enzyme inhibitor (ACEI) or angiotensin-receptor blocker during the measurement period (ARB) who met the Proportion of Days Covered (PDC) threshold of 80 percent.
 - NQF: The percentage of patients 18 years and older who met the proportion of days covered (PDC) threshold of 80% during the measurement year.
- **Gap in Therapy** (PQA): The percentage of prevalent users of any angiotensin-converting enzyme inhibitor (ACEI) or angiotensin-receptor blocker (ARB) who experienced a significant gap (> 30 days) in medication therapy during the measurement period.
- **Persistence Among Members with Coronary Artery Disease at High Risk for Coronary Events** (NQF): To assess the use of and persistence to ACE inhibitors or Angiotensin receptor blockers (ARB) among members with CAD or other atherosclerotic vascular disease (i.e., peripheral arterial disease, atherosclerotic aortic disease and carotid artery disease) who are at high risk for coronary events during a one year period. High-risk comorbidities are defined as heart failure, hypertension, diabetes, or chronic kidney disease (excluding stage V and patients on dialysis).
- **Chronic Kidney Disease**
 - (NQF): Medication Possession Ratio (MPR) for ACEI/ARB therapy for individuals with Chronic Kidney Disease (CKD) and/or diabetes mellitus and hypertension.
 - (NQMC/AMA): percentage of patients aged 18 years and older with a diagnosis of advanced CKD (stage 4 or 5, not receiving RRT), and hypertension and proteinuria who were prescribed ACE inhibitor or ARB therapy during the 12 months reporting period.
 - (NQMC / British Medical Service): the percentage of patients on the CKD register with hypertension and proteinuria who are treated with an angiotensin-converting enzyme inhibitor (ACE-I) or angiotensin receptor blocker (ARB) (unless a contraindication or side effects are recorded).
- **Diabetes**
 - (NQF): Medication Possession Ratio (MPR) for ACEI/ARB therapy for individuals with Chronic Kidney Disease (CKD) and/or diabetes mellitus and hypertension.
 - (NQF): The percentage of patients who were dispensed a medication for diabetes and hypertension who are not receiving an ACEI/ARB medication.
 - (NQF): Medication Possession Ratio (MPR) for Chronic Medications in diabetic individuals over 18 years of age

- (NQF): Percentage of patients with diabetes and hypertension or proteinuria that have a current refill for an angiotensin converting enzyme inhibitor (ACE-I) or angiotensin receptor blocker (ARB)
- (CMS - star ratings): This is defined as the percent of Medicare Part D beneficiaries who were dispensed a medication for diabetes and a medication for hypertension who were receiving an angiotensin converting enzyme inhibitor (ACEI) or angiotensin receptor blocker (ARB) medication. This percentage is calculated as: [(Number of Member-Years of Enrolled Beneficiaries from eligible population who received an ACEI or ARB medication during period measured)/ (Number of Member-Years of Enrolled Beneficiaries in period measured who were dispensed at least one prescription for an oral hypoglycemic agent or insulin and at least one prescription for an antihypertensive agent during the measurement year)].
- (PQA): The percentage of patients who were dispensed a medication for diabetes and a medication for hypertension who are not receiving an angiotensin-converting enzyme inhibitor (ACEI) or angiotensin-receptor blocker (ARB) medication.
- (NQMC / British Medical Service): the percentage of patients with diabetes with a diagnosis of proteinuria or micro-albuminuria who are treated with angiotensin-converting enzyme (ACE) inhibitors (or angiotensin II [A2] antagonists).
- (NQMC/HRSA Health Disparities): percent of patients 55 years and older who have a current prescription for angiotensin-converting enzyme (ACE) inhibitors or angiotensin receptor blocker (ARB) medication.
- **Non-Diabetic Nephropathy**
 - (NQF): Percentage of patients with proteinuria that have a current refill for an angiotensin converting enzyme inhibitor (ACE-I) or angiotensin receptor blocker (ARB)
- **Post MI**
 - (NQF): This measure identifies patients with ST elevation MI (STEMI), or non-ST elevation MI (NSTEMI) plus a history of hypertension, heart failure and/or diabetes prior to the measurement year who are taking an ACEI or an ARB during the measurement year.
 - (NQMC / British Medical Service): the percentage of patients with a history of myocardial infarction who are currently treated with an angiotensin-converting enzyme (ACE) inhibitor or Angiotensin II antagonist.
 - (NQF): Percentage of AMI patients with LVSD and without ACEI contraindications who were prescribed an angiotensin converting enzyme inhibitor (ACEI) for left ventricular systolic dysfunction (LVSD)
 - (NQMC/CMS/JCAHO): percent of patients with LVSD who are prescribed an ACEI or ARB at hospital discharge.
- **Heart Failure**
 - (NQF): Percentage of patients with Heart Failure that are on an ACEI or ARB
 - (NQF/NQMC/AMA): Percentage of patients with HF who also have left ventricular systolic dysfunction (LVSD) who were prescribed ACE inhibitor or ARB therapy.
 - the percentage of patients with a current diagnosis of heart failure due to left ventricular dysfunction (LVD) who are currently treated with angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB), who can tolerate therapy and for whom there is no contraindication.
- **Coronary Artery Disease**

- (NQF/NQMC/AMA): Percentage of patients with Coronary Artery Disease who also have diabetes and/or LSVD who were prescribed ACE inhibitor or ARB therapy.

Cardiovascular - Anticoagulants

- **Deep Vein Thrombosis Anticoagulation >= 3 Months (NQF):** This measure identifies patients with deep vein thrombosis (DVT) on anticoagulation for at least 3 months after the diagnosis
- **Pulmonary Embolism Anticoagulation >= 3 Months (NQF):** This measure identifies patients with pulmonary embolism (PE) on anticoagulation for at least 3 months after the diagnosis.
- **Atrial Fibrillation and other factors**
 - (NQF): Percentage of adult patients with atrial fibrillation and major stroke risk factors on warfarin
 - (NQF): Percentage of patients with HF who also have paroxysmal or chronic atrial fibrillation who were prescribed warfarin therapy.
 - (NQMC/NCQA/AMA): percentage of patients aged 18 years and older with the diagnosis of ischemic stroke or TIA with documented permanent, persistent, or paroxysmal atrial fibrillation who were prescribed an anticoagulant at discharge.
 - (NQMC/AMA): percentage of patients aged 18 years and older with a diagnosis of nonvalvular AF or atrial flutter at high risk for thromboembolism who were prescribed warfarin during the 12 month reporting period.
 - (NQMC/AMA): percentage of patients aged greater than or equal to 18 years with diagnosed heart failure (HF) who also have paroxysmal or chronic atrial fibrillation who were prescribed warfarin therapy.
 - (NQMC/ICSI): percentage of patients with non-valvular atrial fibrillation/flutter with risk factors for thromboembolism having a CHADS2 score of 2 or greater (without contraindications to anticoagulation therapy) who are receiving warfarin.
 - (NQMC/ICSI): percentage of patients (without contraindications to anticoagulation) with paroxysmal, persistent, or permanent atrial fibrillation/flutter with risk factors for thromboembolism who are taking warfarin.
- **Stent drug-eluting clopidogrel (NQF):** This measure identifies patients undergoing percutaneous coronary intervention (PCI) with placement of a drug-eluting intracoronary stent during the first 9 months of the measurement year, who filled a prescription for clopidogrel in the 3 months following stent placement.

Cardiovascular – Beta Blockers

- **Proportion of Days Covered (PQA/NQF):** The percentage of patients who were dispensed a beta-adrenergic blocker during the measurement period who met the PDC threshold of 80 percent.
- **Gap in Therapy (PQA):** The percentage of prevalent users of beta-adrenergic blockers (BB) who experienced a significant gap (> 30 days) in medication therapy during the measurement period.
- **After a Heart Attack**
 - (NQMC/CMS/JCAHO): percent of patients who are prescribed a beta-blocker at hospital discharge.
 - (NQF): Percentage of patients who have a claim indicating beta blocker therapy or who received an ambulatory prescription for beta-blockers rendered within 7 days after discharge.

- (NQF): Percentage of patients whose days' supply of beta blockers dispensed is ≥ 135 days in the 180 days following discharge.
- (NQMC/NCQA): percentage of members 18 years of age and older during the measurement year who were hospitalized and discharged alive from July 1 of the year prior to the measurement year to June 30 of the measurement year with a diagnosis of AMI and who received persistent beta-blocker treatment for six months after discharge.
- (NQF/ NQMC/AMA): Percentage of patients with prior MI at any time who were prescribed beta-blocker therapy.
- (NQF): Percentage of patients who had a myocardial infarction (MI) and are taking a beta blocker.
- **Heart Failure**
 - (NQF/NQMC/AMA): Percentage of patients with HF who also have LVSD who were prescribed beta-blocker therapy.
 - (NQF): Percentage of adult patients with heart failure that are on a beta blocker
 - (NQMC / British Medical Service): the percentage of patients with a current diagnosis of heart failure due to LVD who are currently treated with ACE inhibitor or ARB, who are additionally treated with a beta-blocker licensed for heart failure, or recorded as intolerant to or having a contraindication to beta-blockers.
- **Coronary Heart Disease**
 - (NQMC / British Medical Service): the percentage of patients with coronary heart disease who are currently treated with a beta blocker (unless a contraindication or side-effects are recorded).

Cardiovascular – Calcium Channel Blockers

- **Proportion of Days Covered: Calcium-Channel Blocker (CCB) (PQA):** The percentage of patients who were dispensed a calcium-channel blocker (CCB) during the measurement period who met the PDC threshold of 80 percent.
- **Proportion of Days Covered for Calcium-Channel Blockers (NQF):** The percentage of patients 18 years and older who met the proportion of days covered (PDC) threshold of 80% during the measurement year.
- **Gap in Therapy: Calcium-Channel Blocker (PQA):** The percentage of prevalent users of any calcium-channel blocker (CCB) who experienced a significant gap (> 30 days) in medication therapy during the measurement period.

Cardiovascular – Lipid-lowering medications

- **Proportion of Days Covered (PQA/NQF):** The percentage of patients who were dispensed a medication for dyslipidemia during the measurement period who met the PDC threshold of 80 percent.
- **Gap in Therapy (PQA):** The percentage of prevalent users of medications for dyslipidemia who experience a significant gap (> 30 days) in medication therapy during the measurement period.
- **Coronary Artery Disease**
 - (NQF): Medication Possession Ratio (MPR) for statin therapy for individuals over 18 years of age with coronary artery disease.
 - (NQF/ NQMC/AMA): Percentage of patients with CAD who were prescribed a lipid - lowering therapy

- **Chronic Kidney Disease**
 - (NQF): Percentage of patients with chronic kidney disease and an LDL greater than or equal to 130mg/dl that have a current refill for a lipid lowering agent
- **Atherosclerotic Disease**
 - (NQF): Percentage of adult patients with atherosclerotic disease and an LDL greater than 100 that are taking a lipid lowering agent
- **Diabetes**
 - (NQF): Medication Possession Ratio (MPR) for statin therapy in diabetic individuals over 18 years of age
 - (NQF): Percentage of adult patients with diabetes mellitus and an LDL value greater than 100 mg/dL with a current refill for a lipid lowering agent
 - (NQMC/HRSA Health Disparities): percent of patients 40 years and older who have a current prescription for statins.

Diabetes

- **Medication Possession Ratio (NQF):** Medication Possession Ratio (MPR) for Chronic Medications in diabetic individuals over 18 years of age
- **Proportion of Days Covered**
 - (NQF): The percentage of patients 18 years and older who met the proportion of days covered (PDC) threshold of 80% during the measurement year.
 - (PQA): The percentage of patients who were dispensed an diabetes medication during the measurement period who met the PDC threshold of 80 percent for the following therapeutic categories: Biguanides, Sulfonylureas and Thiazolidinediones. For each product line, report the three rates separately and a total rate.
- **Gap in Therapy (PQA):** The percentage of prevalent users of diabetes medications who experience a significant gap in medication therapy during the measurement period. Report the measure for the following therapeutic categories: biguanides, sulfonylureas and thiazolidinediones. Report the three rates separately and a total rate.
- **Dosing (PQA):** The percentage of patients who were dispensed a dose higher than the daily recommended dose for the following therapeutic categories of oral antihyperglycemics: biguanides, sulfonylureas, and thiazolidinediones. Report each of the three rates separately and as a total rate.
- **Diabetes and Pregnancy: Avoidance of Oral Hypoglycemic Agents (NQF):** This measure identifies pregnant women with diabetes who are not taking an oral hypoglycemic agent.
- **Diabetes and Elevated HbA1C (NQF):** Percentage of patients 18- 75 years with diabetes and an elevated HbA1c that are receiving diabetic treatment (e.g., Metformin)

Hepatitis

- **Hepatitis C: Prescribed Antiviral Therapy** (NQF/ NQMC/AMA): Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who were prescribed peginterferon and ribavirin therapy within the 12 month reporting period
- **Medication Possession Ratios for Hepatitis C** (URAC):
 - Part A: Medication Possession Ratios for New Users
 - Part B: Medication Possession Ratios for Continuing Users
 - Part C: Overall Medication Possession Ratios (New and Continuing Users Combined)

Migraine

- **Adult(s) with frequent use of acute medications that also received prophylactic medications.** (NQF): This measure identifies adults with migraines who are frequently taking acute (abortive) medications and are also taking a prophylactic medication for migraine control.

Osteoporosis

- **Osteopenia and Chronic Steroid Use - Treatment to Prevent Osteoporosis** (NQF): Percentage of patients, who are female and 55 years and older or male and 50 years and older, who have a diagnosis of osteopenia, are on long-term steroids (> 6 months) and who are on osteoporosis therapy.
- **Osteoporosis: Pharmacologic Therapy** (NQF/ NQMC/NCQA/AMA): Percentage of patients aged 50 years and older with a diagnosis of osteoporosis who were prescribed pharmacologic therapy within 12 months
- **Osteoporosis management in women who had a fracture** (NQF): Percentage of women 65 years and older who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat or prevent osteoporosis in the six months after the date of fracture

Pneumonia

- **Empiric Antibiotic for Community-Acquired Bacterial Pneumonia** (NQF/ NQMC/ NCQA/ AMA): Percentage of patients aged 18 years and older with the diagnosis of community-acquired bacterial pneumonia with an appropriate empiric antibiotic prescribed
- **Initial antibiotic selection for community-acquired pneumonia (CAP) in immunocompetent patients** (NQF): Percentage of pneumonia patients 18 years of age or older selected for initial receipts of antibiotics for community-acquired pneumonia (CAP)

Psychiatric

- **Bipolar disorder**
 - (NQF): This measure identifies the percentage of patients with newly diagnosed bipolar disorder who have received at least 1 prescription for a mood-stabilizing agent during the measurement year.
 - (NQMC / Center for Quality Assessment and Improvement in Mental Health): percentage of patients with Bipolar I Disorder with depressive symptoms and behaviors

who have evidence of use of a mood stabilizing or antimanic agent during the first 12 weeks of pharmacotherapy treatment.

- (NQMC / Center for Quality Assessment and Improvement in Mental Health): the percentage of patients with Bipolar I Disorder symptoms and behaviors who received monotherapy with an antidepressant agent during the first 12 weeks of treatment.
- (NQMC / Center for Quality Assessment and Improvement in Mental Health): the percentage of patients with Bipolar I Disorder with mania/hypomania, mixed or cycling symptoms and behaviors who have evidence of use of pharmacotherapy agent with antimanic properties during the first 12 weeks of treatment
- **New Episode of Depression**
 - (NQF/NQMC/NCQA): Effective Acute Phase Treatment: percentage who were treated with antidepressant medication and remained on an antidepressant drug during the entire 84-day Acute Treatment Phase.
 - (NQF/NQMC/NCQA): Effective Continuation Phase Treatment: percentage who remained on an antidepressant drug for at least 180 days.
- **Antipsychotics among members with Schizophrenia (NQF):** Assess the use of and the adherence of antipsychotics among members with schizophrenia during the measurement year

Respiratory

- **Asthma**
 - (NQF/PQA): The percentage of patients with persistent asthma who were dispensed more than 5 canisters of a short-acting beta2 agonist inhaler during the same three-month period.
 - (NQF): The percentage of patients with persistent asthma during the measurement year who were dispensed more than five canisters of short acting beta2 agonist inhalers over a 90-day period and who did not receive controller therapy during the same 90-day period.
 - (NQF): Percentage of patients who were identified as having persistent asthma during the measurement year and the year prior to the measurement year and who were dispensed a prescription for either an inhaled corticosteroid or acceptable alternative medication during the measurement year
 - (NQF): Percentage of patients with asthma who have a refill for a short acting beta agonist in the past 24 months
 - (NQF): Percentage of all patients with mild, moderate, or severe persistent asthma who were prescribed either the preferred long-term control medication (inhaled corticosteroid) or an acceptable alternative treatment
 - (PQA): The percentage of patients with persistent asthma who should be receiving controller therapy but are not.
 - (NQMC/ICSI): percentage of adults with uncontrolled asthma who are on inhaled corticosteroids medication.
- **COPD**
 - (NQF): Percentage of members 40 years of age and older who had an acute inpatient discharge or ER encounter between January 1- November 30 of the measurement year with a principal diagnosis of chronic obstructive pulmonary disease (COPD) and who were dispensed appropriate medications-- a systemic corticosteroid within 14 days of the event and dispensed a bronchodilator within 30 days of the event

- (NQMC/NCQA): percentage of COPD exacerbations for members 40 years of age and older who had an acute inpatient discharge or ED encounter between January 1 to November 30 of the measurement year and who were dispensed a systemic corticosteroid within 14 days of the event.
- (NQF): Percentage of symptomatic patients with COPD who were prescribed an inhaled bronchodilator
- (NQMC/AMA): percentage of patients aged 18 years and older with a diagnosis of COPD and who have an FEV1/FVC less than 70% and have symptoms who were prescribed an inhaled bronchodilator.

Rheumatology

- **Rheumatoid Arthritis**
 - (NQF/ NQMC/NCQA): Percentage of patients 18 years and older, diagnosed with rheumatoid arthritis who have had at least one ambulatory prescription dispensed for a disease modifying antirheumatic drug (DMARD)
 - (NQMC/ Arthritis Foundation): percentage of patients with rheumatoid arthritis and osteoporosis treated with oral or parenteral steroids for whom antiresorptive therapy is prescribed.
- **Non-steroidal anti-inflammatory drug (NSAID) selection** (NQMC/ Arthritis Foundation): percentage of patients who take coumadin and are prescribed an NSAID who receive either a cyclooxygenase 2 (COX-2)-selective NSAID or a nonacetylated salicylate.

Appendix C. CAHPS 2011 Medicare Stand Alone PDP Survey

As submitted for approval to OMB on March 4, 2010. Accessed at <http://www.cms.gov/PaperworkReductionActof1995/Downloads/CMS-R-246.zip>

YOUR HEALTH PLAN

1. Our records show that in 2010 your Medicare prescription drugs were covered by [INSERT PLAN NAME HERE]. Is that right?

- Yes → If Yes, Go to Question 3
- No

2. Please write below the name of the Medicare prescription drug plan you had in 2010 and complete the rest of the survey based on the experiences you had with that plan. (Please print)

3. Each fall Medicare Prescription Drug Plans send out notices that describes any changes in their plan. Since September 2010, has [INSERT PLAN NAME HERE] sent you this kind of notice?

- Yes
- No
- Don't know

4. When you sign up for a Medicare Prescription Drug Plan, you are given a document that describes your specific benefits under the plan. This document also describes whether there are any limits on how much or what type of prescriptions you can have in a year and your rights as a plan member. Has [INSERT PLAN NAME HERE] ever given you a document with this kind of information?

- Yes
- No
- Don't know

5. An insurance agent or broker sells insurance for your health, your home, or your car, or prescription drugs. Did an insurance agent or broker ever call you without your asking them to, to tell you about insurance for health care or prescription medicines?

- Yes
- No

6. Did an insurance agent or broker ever visit your home without your asking them to, to tell you about insurance for health care or prescription medicines?

- Yes
- No

7. Did an insurance agent or broker ever switch you to a different Medicare Prescription Drug Plan without your permission?

- Yes
- No

YOUR PRESCRIPTION DRUG PLAN

Now, we would like to ask you some additional questions about the prescription drug coverage you get through [INSERT PLAN NAME HERE].

8. Customer service is information you get from staff about what is covered and how to use the plan. In the last 6 months, did you try to get information or help from [INSERT PLAN NAME HERE]'s customer service about prescription drugs?

- Yes
- No → If No, Go to Question 13

9. In the last 6 months, how often did [INSERT PLAN NAME HERE]'s customer service give you the information or help you needed about prescription drugs?

- Never
- Sometimes
- Usually
- Always
- I did not try to get information or help from my health plan's customer service in the last 6 months.

10. In the last 6 months, how often did [INSERT PLAN NAME HERE]'s customer service staff treat you with courtesy and respect when you tried to get information or help about prescription drugs?

- Never
- Sometimes
- Usually
- Always
- I did not try to get information or help from my health plan's customer service in the last 6 months.

11. In the last 6 months, did you try to get information from [INSERT PLAN NAME HERE] about which prescription medicines were covered?

- Yes
- No → If No, Go to Question 13

12. In the last 6 months, how often did [INSERT PLAN NAME HERE] give you all the information you needed about which prescription medicines were covered?

- Never
- Sometimes
- Usually
- Always
- I did not try to get information about which prescription medicines were covered in the last 6 months.

13. In the last 6 months, did you try to get information from [INSERT PLAN NAME HERE] about how much you would have to pay for your prescription medicines?

- Yes
- No → If No, Go to Question 15

14. In the last 6 months, how often did [INSERT PLAN NAME HERE] give you all the information you needed about how much you would have to pay for your prescription medicine?

- Never
- Sometimes
- Usually
- Always
- I did not try to get information about how much I would have to pay for prescription medicines in the last 6 months.

15. In the last 6 months, how many different prescription medicines did you fill or have refilled?

- None
- 1 to 2 medicines
- 3 to 5 medicines
- 6 or more medicines

16. In the last 6 months, did a doctor prescribe a medicine for you that [INSERT PLAN NAME HERE] did not cover?

- Yes
- No → If No, Go to Question 19

17. When this happened, did you contact [INSERT PLAN NAME HERE] to ask them to cover the medicine your doctor prescribed?

- Yes
- No → If No, Go to Question 19
- All my prescribed medicines were covered.

18. When you contacted [INSERT PLAN NAME HERE] about the decision not to cover a prescription medicine did they ...

Please mark one or more.

- Tell you that you can file an appeal
- Offer to send you forms that you need to file an appeal
- Suggest how to resolve your complaint
- Listen to your complaint but did not help to resolve it
- Discourage you from taking action
- Do none of these things
- All my prescribed medicines were covered

19. In the last 6 months, how often was it easy to use [INSERT PLAN NAME HERE] to get the medicines your doctor prescribed?

- Never
- Sometimes
- Usually
- Always
- I did not use my health plan to get any prescription medicines in the last 6 months.

20. In the last 6 months, did you ever use [INSERT PLAN NAME HERE] to fill a prescription at a local pharmacy?

- Yes
- No → If No, Go to Question 22

21. In the last 6 months, how often was it easy to use [INSERT PLAN NAME HERE] to fill a prescription at a local pharmacy?

- Never
- Sometimes
- Usually
- Always
- I did not use my health plan to fill a prescription at a local pharmacy in the last 6 months.

22. In the last 6 months, did you ever use [INSERT PLAN NAME HERE] to fill any prescriptions by mail?

- Yes
- No → If No, Go to Question 24

23. In the last 6 months, how often was it easy to use [INSERT PLAN NAME HERE] to fill prescriptions by mail?

- Never
- Sometimes
- Usually
- Always
- I did not use my health plan to fill a prescription by mail in the last 6 months.

24. Using any number from 0 to 10, where 0 is the worst prescription drug plan possible and 10 is the best prescription drug plan possible, what number would you use to rate [INSERT PLAN NAME HERE] for coverage of prescription drugs?

- 0 Worst prescription drug plan possible
- 1
- ...
- 9
- 10 Best prescription drug plan possible

25. Would you recommend [INSERT PLAN NAME HERE] for coverage of prescription drugs to other people like yourself?

- Definitely yes
- Somewhat yes
- Somewhat no
- Definitely no

26. Medicare has a special program to give extra help to individuals with low or limited incomes to pay for prescription drug costs, like plan premiums and co-pays for prescribed medicines. Have you signed up for this extra help program?

- Yes
- No → If No, Go to Question 30
- Don't know → If Don't know, Go to Question 30

27. In the last 6 months, how often were you able to use Medicare's extra help program when you refilled a prescription for a medicine you had taken before?

- Never
- Sometimes
- Usually
- Always
- I did not refill any prescription in the last 6 months.

28. In the last 6 months, did pharmacy staff tell you that you needed to provide proof that you qualify for Medicare's extra help program?

- Yes
- No

29. In the last 6 months, have you ever gone without a prescribed medicine because the pharmacy's records didn't show you were signed up for Medicare's extra help program?

- Yes
- No

ABOUT YOU

30. In general, how would you rate your overall health?

- Excellent
- Very good
- Good
- Fair
- Poor

31. In general, how would you rate your overall mental health?

Excellent

- Very good
- Good
- Fair
- Poor

32. In the past 12 months, have you seen a doctor or other health provider 3 or more times for the same condition or problem?

- Yes
- No → If No, Go to Question 35

33. Is this a condition or problem that has lasted for at least 3 months?

- Yes
- No

34. Do you now need or take medicine prescribed by a doctor?

- Yes
- No → If No, Go to Question 36

35. Is this to treat a condition that has lasted for at least 3 months?

- Yes
- No

36. In the last 6 months, did you ever delay or not fill a prescription because you felt that you could not afford it?

- Yes
- No
- My doctor did not prescribe any medicines for me in the last 6 months

37. How confident are you that you can identify when it is necessary for you to get medical care?
- Very confident
 - Confident
 - Somewhat confident
 - Not at all confident
38. Because of any impairment or health problem, do you need the help of other persons with your personal care needs, such as eating, dressing, or getting around the house?
- Yes
 - No
39. Because of any impairment or health problem, do you need help with your routine needs, such as everyday household chores, doing necessary business, shopping, or getting around for other purposes?
- Yes
 - No
40. Do you have a physical or medical condition that seriously interferes with your independence, participation in the community, or quality of life?
- Yes
 - No
41. Has a doctor ever told you that you had any of the following conditions?
- a. A heart attack?
 - b. Angina or coronary heart disease?
 - c. A stroke?
 - d. Cancer, other than skin cancer?
 - e. Emphysema, asthma or COPD (chronic obstructive pulmonary disease)?
 - f. Any kind of diabetes or high blood sugar?
42. What is your age?
- 18 to 24
 - 25 to 34
 - 35 to 44
 - 45 to 54
 - 55 to 64
 - 65 to 69
 - 70 to 74
 - 75 to 79
 - 80 to 84
 - 85 or older
43. Are you male or female?
- Male
 - Female
44. What is the highest grade or level of school that you have completed?
- 8th grade or less
 - Some high school, but did not graduate
 - High school graduate or GED
 - Some college or 2-year degree
 - 4-year college graduate
 - More than 4-year college degree
45. Are you of Hispanic or Latino origin or descent?

- Yes, Hispanic or Latino
 - No, not Hispanic or Latino
46. What is your race? Please mark one or more.
- White
 - Black or African-American
 - Asian
 - Native Hawaiian or other Pacific Islander
 - American Indian or Alaska Native
47. Did someone help you complete this survey?
- Yes
 - No → If No, Go to Question 49
48. How did that person help you? Please mark one or more.
- Read the questions to me
 - Wrote down the answers I gave
 - Answered the questions for me
 - Translated the questions into my language
 - Helped in some other way
49. Do you live alone?
- Yes, I live alone
 - No, I live with others

Earlier in the survey you were asked to indicate whether you have any limitations in your activities. We are now going to ask a few additional questions in this area.

50. Because of a health or physical problem are you unable to do or have any difficulty doing the following activities? (Please mark one response for each activity.)

- a. Bathing
- b. Dressing
- c. Eating
- d. Getting in or out of chairs
- e. Walking
- f. Using the toilet

Appendix D. Potentially Inappropriate Medications for the Elderly

The Beers Criteria

Table 1. 2002 Criteria for Potentially Inappropriate Medication Use in Older Adults: Independent of Diagnoses or Conditions

Drug	Concern	Severity Rating (High or Low)
Propoxyphene (Darvon) and combination products (Darvon with ASA, Darvon-N, and Darvocet-N)	Offers few analgesic advantages over acetaminophen, yet has the adverse effects of other narcotic drugs.	Low
Indomethacin (Indocin and Indocin SR)	Of all available nonsteroidal anti-inflammatory drugs, this drug produces the most CNS adverse effects.	High
Pentazocine (Talwin)	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.	High
Trimethobenzamide (Tigan)	One of the least effective antiemetic drugs, yet it can cause extrapyramidal adverse effects.	High
Muscle relaxants and antispasmodics: methocarbamol (Robaxin), carisoprodol (Soma), chlorzoxazone (Paraflex), metaxalone (Skelaxin), cyclobenzaprine (Flexeril), and oxybutynin (Ditropan). Do not consider the extended-release Ditropan XL.	Most muscle relaxants and antispasmodic drugs are poorly tolerated by elderly patients, since these cause anticholinergic adverse effects, sedation, and weakness. Additionally, their effectiveness at doses tolerated by elderly patients is questionable.	High
Flurazepam (Dalmane)	This benzodiazepine hypnotic has an extremely long half-life in elderly patients (often days), producing prolonged sedation and increasing the incidence of falls and fracture. Medium- or short-acting benzodiazepines are preferable.	High
Amitriptyline (Elavil), chlordiazepoxide-amitriptyline (Limbitrol), and perphenazine-amitriptyline (Triavil)	Because of its strong anticholinergic and sedation properties, amitriptyline is rarely the antidepressant of choice for elderly patients.	High
Doxepin (Sinequan)	Because of its strong anticholinergic and sedating properties, doxepin is rarely the antidepressant of choice for elderly patients.	High
Meprobamate (Miltown and Equanil)	This is a highly addictive and sedating anxiolytic. Those using meprobamate for prolonged periods may become addicted and may need to be withdrawn slowly.	High
Doses of short-acting benzodiazepines: doses greater than lorazepam (Ativan), 3 mg; oxazepam (Serax), 60 mg; alprazolam (Xanax), 2 mg; temazepam (Restoril), 15 mg; and triazolam (Halcion), 0.25 mg	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.	High
Long-acting benzodiazepines: chlordiazepoxide (Librium), chlordiazepoxide-amitriptyline (Limbitrol) clidinium-chlordiazepoxide (Librax), diazepam (Valium), quazepam (Doral), halazepam (Paxipam), and chlorazepate (Tranxene)	These drugs have a long half-life in elderly patients (often several days), producing prolonged sedation and increasing the risk of falls and fractures. Short- and intermediate-acting benzodiazepines are preferred if a benzodiazepine is required.	High
Disopyramide (Norpace and Norpace CR)	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.	High
Digoxin (Lanoxin) (should not exceed >0.125 mg/d except when treating atrial arrhythmias)	Decreased renal clearance may lead to increased risk of toxic effects.	Low
Short-acting dipyridamole (Persantine). 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 hypotension.	Low
Methyldopa (Aldomet) and methyldopa-hydrochlorothiazide (Aldoril)	May cause bradycardia and exacerbate depression in elderly patients.	High
Reserpine at doses >0.25 mg	May induce depression, impotence, sedation, and orthostatic hypotension.	Low
Chlorpropamide (Diabinese)	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.	High
Gastrointestinal antispasmodic drugs: dicyclomine (Bentyl), hyoscyamine (Levsin and Levsinex), propantheline (Pro-Banthine), belladonna alkaloids (Donnatal and others), and clidinium-chlordiazepoxide (Librax)	GI antispasmodic drugs are highly anticholinergic and have uncertain effectiveness. These drugs should be avoided (especially for long-term use).	High

Anticholinergics and antihistamines: chlorpheniramine (Chlor-Trimeton), diphenhydramine (Benadryl), hydroxyzine (Vistaril and Atarax), cyproheptadine (Periactin), promethazine (Phenergan), tripeleonnamine, dexchlorpheniramine (Polaramine)	All nonprescription and many prescription antihistamines may have potent anticholinergic properties. Nonanticholinergic antihistamines are preferred in elderly patients when treating allergic reactions.	High
Diphenhydramine (Benadryl)	May cause confusion and sedation. Should not be used as a hypnotic, and when used to treat emergency allergic reactions, it should be used in the smallest possible dose.	High
Ergot mesyloids (Hydergine) and cycloclandate (Cyclospasmol)	Have not been shown to be effective in the doses studied.	Low
Ferrous sulfate >325 mg/d	Doses >325 mg/d do not dramatically increase the amount absorbed but greatly increase the incidence of constipation.	Low
All barbiturates (except phenobarbital) except when used to control seizures	Are highly addictive and cause more adverse effects than most sedative or hypnotic drugs in elderly patients.	High
Meperidine (Demerol)	Not an effective oral analgesic in doses commonly used. May cause confusion and has many disadvantages to other narcotic drugs.	High
Ticlopidine (Ticlid)	Has been shown to be no better than aspirin in preventing clotting and may be considerably more toxic. Safer, more effective alternatives exist.	High
Ketorolac (Toradol)	Immediate and long-term use should be avoided in older persons, since a significant number have asymptomatic GI pathologic conditions.	High
Amphetamines and anorexic agents	These drugs have potential for causing dependence, hypertension, angina, and myocardial infarction.	High
Long-term use of full-dosage, longer half-life, non-COX-selective NSAIDs: naproxen (Naprosyn, Avaprox, and Aleve), oxaprozin (Daypro), and piroxicam (Feldene)	Have the potential to produce GI bleeding, renal failure, high blood pressure, and heart failure.	High
Daily fluoxetine (Prozac)	Long half-life of drug and risk of producing excessive CNS stimulation, sleep disturbances, and increasing agitation. Safer alternatives exist.	High
Long-term use of stimulant laxatives: bisacodyl (Dulcolax), cascara sagrada, and Neoloid except in the presence of opiate analgesic use	May exacerbate bowel dysfunction.	High
Amiodarone (Cordarone)	Associated with QT interval problems and risk of provoking torsades de pointes. Lack of efficacy in older adults.	High
Orphenadrine (Norflex)	Causes more sedation and anticholinergic adverse effects than safer alternatives.	High
Guanethidine (Ismelin)	May cause orthostatic hypotension. Safer alternatives exist.	High
Guanadrel (Hylorel)	May cause orthostatic hypotension.	High
Cycloclandate (Cyclospasmol)	Lack of efficacy.	Low
Isoxsurpine (Vasodilan)	Lack of efficacy.	Low
Nitrofurantoin (Macroclant)	Potential for renal impairment. Safer alternatives available.	High
Doxazosin (Cardura)	Potential for hypotension, dry mouth, and urinary problems.	Low
Methyltestosterone (Android, Virilon, and Testrad)	Potential for prostatic hypertrophy and cardiac problems.	High
Thioridazine (Mellaril)	Greater potential for CNS and extrapyramidal adverse effects.	High
Mesoridazine (Serentil)	CNS and extrapyramidal adverse effects.	High
Short acting nifedipine (Procardia and Adalat)	Potential for hypotension and constipation.	High
Clonidine (Catapres)	Potential for orthostatic hypotension and CNS adverse effects.	Low
Mineral oil	Potential for aspiration and adverse effects. Safer alternatives available.	High
Cimetidine (Tagamet)	CNS adverse effects including confusion.	Low
Ethacrynic acid (Edecrin)	Potential for hypertension and fluid imbalances. Safer alternatives available.	Low
Desiccated thyroid	Concerns about cardiac effects. Safer alternatives available.	High
Amphetamines (excluding methylphenidate hydrochloride and anorexics)	CNS stimulant adverse effects.	High
Estrogens only (oral)	Evidence of the carcinogenic (breast and endometrial cancer) potential of these agents and lack of cardioprotective effect in older women.	Low

Abbreviations: CNS, central nervous system; COX, cyclooxygenase; GI, gastrointestinal; NSAIDs, nonsteroidal anti-inflammatory drugs; SIADH, syndrome of inappropriate antidiuretic hormone secretion.

Source: Fick DM, Cooper JW, Wade WE, Waller JL, Maclean JR, Beers MH. "Updating the Beers criteria for potentially inappropriate medication use in older adults: results of a US consensus panel of experts." *Archives of Internal Medicine* 163 (2003):2716-2724.

Table 2. 2002 Criteria for Potentially Inappropriate Medication Use in Older Adults: Considering Diagnoses or Conditions

Disease or Condition	Drug	Concern	Severity Rating (High or Low)
Heart failure	Disopyramide (Norpace), and high sodium content drugs (sodium and sodium salts [alginate bicarbonate, biphosphate, citrate, phosphate, salicylate, and sulfate])	Negative inotropic effect. Potential to promote fluid retention and exacerbation of heart failure.	High
Hypertension	Phenylpropranolamine hydrochloride (removed from the market in 2001), pseudoephedrine; diet pills, and amphetamines	May produce elevation of blood pressure secondary to sympathomimetic activity.	High
Gastric or duodenal ulcers	NSAIDs and aspirin (>325 mg) (coxibs excluded)	May exacerbate existing ulcers or produce new/additional ulcers.	High
Seizures or epilepsy	Clozapine (Clozaril), chlorpromazine (Thorazine), thioridazine (Mellaril), and thiothixene (Navane)	May lower seizure thresholds.	High
Blood clotting disorders or receiving anticoagulant therapy	Aspirin, NSAIDs, dipyridamole (Persantin), ticlopidine (Ticlid), and clopidogrel (Plavix)	May prolong clotting time and elevate INR values or inhibit platelet aggregation, resulting in an increased potential for bleeding.	High
Bladder outflow obstruction	Anticholinergics and antihistamines, gastrointestinal antispasmodics, muscle relaxants, oxybutynin (Ditropan), flavoxate (Urispas), anticholinergics, antidepressants, decongestants, and tolterodine (Detrol)	May decrease urinary flow, leading to urinary retention.	High
Stress incontinence	α-Blockers (Doxazosin, Prazosin, and Terazosin), anticholinergics, tricyclic antidepressants (imipramine hydrochloride, doxepin hydrochloride, and amitriptyline hydrochloride), and long-acting benzodiazepines	May produce polyuria and worsening of incontinence.	High
Arrhythmias	Tricyclic antidepressants (imipramine hydrochloride, doxepin hydrochloride, and amitriptyline hydrochloride)	Concern due to proarrhythmic effects and ability to produce QT interval changes.	High
Insomnia	Decongestants, theophylline (Theodur), methylphenidate (Ritalin), MAOIs, and amphetamines	Concern due to CNS stimulant effects.	High
Parkinson disease	Metoclopramide (Reglan), conventional antipsychotics, and tacrine (Cognex)	Concern due to their antidopaminergic/cholinergic effects.	High
Cognitive impairment	Barbiturates, anticholinergics, antispasmodics, and muscle relaxants. CNS stimulants: dextroAmphetamine (Adderall), methylphenidate (Ritalin), methamphetamine (Desoxyn), and pemolin	Concern due to CNS-altering effects.	High
Depression	Long-term benzodiazepine use. Sympatholytic agents: methyl dopa (Aldomet), reserpine, and guanethidine (Ismelin)	May produce or exacerbate depression.	High
Anorexia and malnutrition	CNS stimulants: DextroAmphetamine (Adderall), methylphenidate (Ritalin), methamphetamine (Desoxyn), pemolin, and fluoxetine (Prozac)	Concern due to appetite-suppressing effects.	High
Syncope or falls	Short- to intermediate-acting benzodiazepine and tricyclic antidepressants (imipramine hydrochloride, doxepin hydrochloride, and amitriptyline hydrochloride)	May produce ataxia, impaired psychomotor function, syncope, and additional falls.	High
SIADH/hyponatremia	SSRIs: fluoxetine (Prozac), citalopram (Celexa), fluvoxamine (Luvox), paroxetine (Paxil), and sertraline (Zoloft)	May exacerbate or cause SIADH.	Low
Seizure disorder	Bupropion (Wellbutrin)	May lower seizure threshold.	High
Obesity	Olanzapine (Zyprexa)	May stimulate appetite and increase weight gain.	Low
COPD	Long-acting benzodiazepines: chlordiazepoxide (Librium), chlordiazepoxide-amitriptyline (Limbitrol), clidinium-chlordiazepoxide (Librax), diazepam (Valium), quazepam (Doral), halazepam (Paxipam), and chlorazepate (Tranxene). β-blockers: propranolol	CNS adverse effects. May induce respiratory depression. May exacerbate or cause respiratory depression.	High
Chronic constipation	Calcium channel blockers, anticholinergics, and tricyclic antidepressant (imipramine hydrochloride, doxepin hydrochloride, and amitriptyline hydrochloride)	May exacerbate constipation.	Low

Abbreviations: CNS, central nervous systems; COPD, chronic obstructive pulmonary disease; INR, international normalized ratio; MAOIs, monoamine oxidase inhibitors; NSAIDs, nonsteroidal anti-inflammatory drugs; SIADH, syndrome of inappropriate antidiuretic hormone secretion; SSRIs, selective serotonin reuptake inhibitors.

Source: Fick DM, Cooper JW, Wade WE, Waller JL, Maclean JR, Beers MH. "Updating the Beers criteria for potentially inappropriate medication use in older adults: results of a US consensus panel of experts." *Archives of Internal Medicine* 163 (2003):2716-2724.

NCQA High-Risk Medications in the Elderly

We matched the NDCs provided by NCQA for their measure Use of High-Risk Medications in the Elderly to the Part D Formulary Reference File, resulting in the following list.

ACETAMINOPHEN-PENTAZOCINE	LIQUADD
ACETAMINOPHEN-PROPOXYPHENE HCL & NAPSYLATE	LOMOTIL
ADDERALL & ADDERALL XR	LONOX
AMITRIPTYLINE-CHLORDIAZEPOXIDE	MACROBID
AMPHETAMINE-DEXTROAMPHETAMINE	MACRODANTIN
AMRIX	MENEST
ANDROID	MEPERIDINE HCL
ASA/CAFFEINE/ORPHENADRINE	MEPROBAMATE
ASA/CARISOPRODOL/CODEINE PHOSPHATE	METADATE CD & METADATE ER
ASPIRIN-CARISOPRODOL	METHITEST
ATROPINE SO4-DIPHENOXYLATE HCL	METHOCARBAMOL
BALACET	METHYLIN, METHYLIN ER
BENTYL	METHYLPHENIDATE HCL & HCL SR
CARISOPRODOL	MOTOFEN
CENESTIN	NALOXONE HCL-PENTAZOCINE HCL
CHLORPROPAMIDE	NIFEDIPINE
CHLORZOXAZONE	NITROFURANTOIN MACROCRYSTALS
CONCERTA	NORFLEX
CYCLOBENZAPRINE HCL	OGEN 0.625, OGEN 1.25, & OGEN 2.5
CYPROHEPTADINE HCL	ORPHENADRINE CITRATE
DARVOCET A500 & DARVOCET-N	PARAFON FORTE DSC
DARVON & DARVON-N	PERSANTINE
DAYTRANA	PHENERGAN
DEMEROL HCL	PREMARIN
DESOXYN	PREMPHASE
DEXCHLORPHENIRAMINE MALEATE	PREMPRO
DEXEDRINE SPANSULE	PROCARDIA
DEXMETHYLPHENIDATE HCL	PROMETHAZINE HCL & PROMETHAZINE VC
DEXTROAMPHETAMINE SULFATE	PROPANTHELINE BROMIDE
DICYCLOMINE HCL	PROPOXYPHENE HCL
DIPHENHYDRAMINE HCL	RITALIN, RITALIN LA, & RITALIN-SR
DIPYRIDAMOLE	ROBAXIN
ENJUVIA	ROBAXIN-750
EQUAGESIC	SKELAXIN
ERGOLOID MESYLATES	SOMA
ESTROPIPATE	TALACEN
FEXMID	TALWIN, TALWIN LACTATE, & TALWIN NX
FLEXERIL	TESTRED
FOCALIN & FOCALIN XR	THIORIDAZINE HCL
FURADANTIN	TIGAN
HYDROXYZINE HCL & HYDROXYZINE PAMOATE	TRANSDERM-SCOP
KETOROLAC TROMETHAMINE	TRIMETHOBENZAMIDE HCL
LIMBITROL	VISTARIL

SOURCE: NCQA, "HEDIS 2010 Final NDC Lists." <http://www.ncqa.org/tabid/1091/Default.aspx>

The Improving Prescribing in the Elderly Tool

“The following medications represent potentially inappropriate prescriptions in an elderly individual:

- Beta-blocker and chronic obstructive airways disease
- Beta-blocker and congestive heart failure
- Calcium channel blocker (excluding amlodipine and felodimine) and congestive heart failure
- Thiazide diuretic and gout
- Long half-life benzodiazepine (chlordiazepoxide, clorazepate, diazepam, flurazepam, clonazepam, nitrazepam)
- Tricyclic antidepressant and glaucoma
- Tricyclic antidepressant and heart block
- Tricyclic antidepressant with active metabolites (imipramine, doxepin, or amitriptyline)
- Methylphenidate for depression
- Nonsteroidal anti-inflammatory drugs and peptic ulcer disease
- Nonsteroidal anti-inflammatory drugs and hypertension
- Long term use of nonsteroidal anti-inflammatory drugs for osteoarthritis
- Anticholinergic drugs to treat side effects of antipsychotic medications
- Long term diphenoxylate to treat diarrhea”

Source: Christopher T Naugler, Chris Brymer, Paul Stolee, Zora Arcese. “Development and validation of an Improving Prescribing in the Elderly Tool.” Canadian Journal of Clinical Pharmacology Vol. 7, No. 2 (2000): 103-107.

Screening Tool of Older People's Potentially Inappropriate Prescriptions (STOPP)

"The following drug prescriptions are potentially inappropriate in persons aged ≥ 65 years of age:

A. Cardiovascular System

1. Digoxin at a long-term dose $> 125\mu\text{g}/\text{day}$ with impaired renal function* (*increased risk of toxicity*).
2. Loop diuretic for dependent ankle oedema only i.e. no clinical signs of heart failure (*no evidence of efficacy, compression hosiery usually more appropriate*).
3. Loop diuretic as first-line monotherapy for hypertension (*safer, more effective alternatives available*).
4. Thiazide diuretic with a history of gout (*may exacerbate gout*).
5. Beta-blocker with Chronic Obstructive Pulmonary Disease (COPD) (*risk of increased bronchospasm*).
6. Beta-blocker in combination with verapamil (*risk of symptomatic heart block*).
7. Use of diltiazem or verapamil with NYHA Class III or IV heart failure (*may worsen heart failure*).
8. Calcium channel blockers with chronic constipation (*may exacerbate constipation*).
9. Use of aspirin and warfarin in combination without histamine H₂ receptor antagonist (except cimetidine because of interaction with warfarin) or proton pump inhibitor (*high risk of gastrointestinal bleeding*).
10. Dipyridamole as monotherapy for cardiovascular secondary prevention (*no evidence for efficacy*).
11. Aspirin with a past history of peptic ulcer disease without histamine H₂ receptor antagonist or Proton Pump Inhibitor (*risk of bleeding*).
12. 12. Aspirin at dose $> 150\text{mg}$ day (*increased bleeding risk, no evidence for increased efficacy*).
13. Aspirin with no history of coronary, cerebral or peripheral vascular symptoms or occlusive event (*not indicated*).
14. Aspirin to treat dizziness not clearly attributable to cerebrovascular disease (*not indicated*).
15. Warfarin for first, uncomplicated deep venous thrombosis for longer than 6 months duration (*no proven added benefit*).
16. Warfarin for first uncomplicated pulmonary embolus for longer than 12 months duration (*no proven benefit*).
17. Aspirin, clopidogrel, dipyridamole or warfarin with concurrent bleeding disorder (*high risk of bleeding*).

B. Central Nervous System and Psychotropic Drugs.

1. Tricyclic antidepressants (TCA's) with dementia (*risk of worsening cognitive impairment*).
2. TCA's with glaucoma (*likely to exacerbate glaucoma*).
3. TCA's with cardiac conductive abnormalities (*pro-arrhythmic effects*).
4. TCA's with constipation (*likely to worsen constipation*).
5. TCA's with an opiate or calcium channel blocker (*risk of severe constipation*).
6. TCA's with prostatism or prior history of urinary retention (*risk of urinary retention*).

7. Long-term (i.e. > 1 month), long-acting benzodiazepines e.g. clordiazepoxide, fluzepam, nitrazepam, chlorazepate and benzodiazepines with long-acting metabolites e.g. diazepam (*risk of prolonged sedation, confusion, impaired balance, falls*).
8. Long-term (i.e. > 1 month) neuroleptics as long-term hypnotics (*risk of confusion, hypotension, extra-pyramidal side effects, falls*).
9. Long-term neuroleptics (> 1 month) in those with parkinsonism (*likely to worsen extra-pyramidal symptoms*).
10. Phenothiazines in patients with epilepsy (*may lower seizure threshold*).
11. Anticholinergics to treat extra-pyramidal side-effects of neuroleptic medications (*risk of anticholinergic toxicity*).
12. Selective serotonin re-uptake inhibitors (SSRI's) with a history of clinically significant hyponatraemia (*non-iatrogenic hyponatraemia <130mmol/l within the previous 2 months*).
13. Prolonged use (> 1 week) of first generation antihistamines i.e. diphenhydramine, chlorpheniramine, cyclizine, promethazine (*risk of sedation and anti-cholinergic side effects*).

C. Gastrointestinal System

1. Diphenoxylate, loperamide or codeine phosphate for treatment of diarrhoea of unknown cause (*risk of delayed diagnosis, may exacerbate constipation with overflow diarrhoea, may precipitate toxic megacolon in inflammatory bowel disease, may delay recovery in unrecognised gastroenteritis*).
2. Diphenoxylate, loperamide or codeine phosphate for treatment of severe infective gastroenteritis i.e. bloody diarrhoea, high fever or severe systemic toxicity (*risk of exacerbation or protraction of infection*).
3. Prochlorperazine (Stemetil) or metoclopramide with Parkinsonism (*risk of exacerbating Parkinsonism*).
4. PPI for peptic ulcer disease at full therapeutic dosage for > 8 weeks (*dose reduction or earlier discontinuation indicated*).
5. Anticholinergic antispasmodic drugs with chronic constipation (*risk of exacerbation of constipation*).

D. Respiratory System.

1. Theophylline as monotherapy for COPD. (*safer, more effective alternative; risk of adverse effects due to narrow therapeutic index*)
2. Systemic corticosteroids instead of inhaled corticosteroids for maintenance therapy in moderate-severe COPD (*unnecessary exposure to long-term side-effects of systemic steroids*).
3. Nebulised ipratropium with glaucoma (*may exacerbate glaucoma*).

E. Musculoskeletal System

1. Non-steroidal anti-inflammatory drug (NSAID) with history of peptic ulcer disease or gastrointestinal bleeding, unless with concurrent histamine H2 receptor antagonist, PPI or misoprostol (*risk of peptic ulcer relapse*).
2. NSAID with moderate-severe hypertension (moderate: 160/100mmHg – 179/109mmHg; severe: ≥180/110mmHg) (*risk of exacerbation of hypertension*).
3. NSAID with heart failure (*risk of exacerbation of heart failure*).
4. Long-term use of NSAID (>3 months) for relief of mild joint pain in osteoarthritis (*simple analgesics preferable and usually as effective for pain relief*)

5. Warfarin and NSAID together (*risk of gastrointestinal bleeding*).
6. NSAID with chronic renal failure* (*risk of deterioration in renal function*).
7. Long-term corticosteroids (>3 months) as monotherapy for rheumatoid arthritis or osterarthritis (*risk of major systemic corticosteroid side-effects*).
8. Long-term NSAID or colchicine for chronic treatment of gout where there is no contraindication to allopurinol (*allopurinol first choice prophylactic drug in gout*)

F. Urogenital System

1. Bladder antimuscarinic drugs with dementia (*risk of increased confusion, agitation*).
2. Antimuscarinic drugs with chronic glaucoma (*risk of acute exacerbation of glaucoma*).
3. Antimuscarinic drugs with chronic constipation (*risk of exacerbation of constipation*).
4. Antimuscarinic drugs with chronic prostatism (*risk of urinary retention*).
5. Alpha-blockers in males with frequent incontinence i.e. one or more episodes of incontinence daily (*risk of urinary frequency and worsening of incontinence*).
6. Alpha-blockers with long-term urinary catheter *in situ* i.e. more than 2 months (*drug not indicated*).

G. Endocrine System

1. Glibenclamide or chlorpropamide with type 2 diabetes mellitus (*risk of prolonged hypoglycaemia*).
2. Beta-blockers in those with diabetes mellitus and frequent hypoglycaemic episodes i.e. ≥ 1 episode per month (*risk of masking hypoglycaemic symptoms*).
3. Oestrogens with a history of breast cancer or venous thromboembolism (*increased risk of recurrence*)
4. Oestrogens without progestogen in patients with intact uterus (*risk of endometrial cancer*).

H. Drugs that adversely affect those prone to falls (≥ 1 fall in past three months)

1. Benzodiazepines (*sedative, may cause reduced sensorium, impair balance*).
2. Neuroleptic drugs (*may cause gait dyspraxia, Parkinsonism*).
3. First generation antihistamines (*sedative, may impair sensorium*).
4. Vasodilator drugs known to cause hypotension in those with persistent postural hypotension i.e. recurrent $> 20\text{mmHg}$ drop in systolic blood pressure (*risk of syncope, falls*).
5. Long-term opiates in those with recurrent falls (*risk of drowsiness, postural hypotension, vertigo*).

I. Analgesic Drugs

1. Use of long-term powerful opiates e.g. morphine or fentanyl as first line therapy for mild-moderate pain (*WHO analgesic ladder not observed*).
2. Regular opiates for more than 2 weeks in those with chronic constipation without concurrent use of laxatives (*risk of severe constipation*).
3. Long-term opiates in those with dementia unless indicated for palliative care or management of moderate/severe chronic pain syndrome (*risk of exacerbation of cognitive impairment*).

J. Duplicate Drug Classes

Any duplicate drug class prescription e.g. two concurrent opiates, NSAID's, SSRI's, loop diuretics, ACE inhibitors (*optimisation of monotherapy within a single drug class should be observed prior to considering a new class of drug.*)”

Source: Gallagher and O'Mahony, “STOPP (Screening Tool of Older Persons' potentially inappropriate Prescriptions): application to acutely ill elderly patients and comparison with Beers' criteria: Appendix 1.” *Age and Ageing* vol. 37 no. 6 (2008): 673