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**Ready for Pick-Up: Reducing Primary  
Medication Non-Adherence**  
*A New Prescription for Health Care Improvement*

A NEHI Issue Brief | October 2014

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*An issue brief on key issues in the adoption and utilization of the new pharmacy quality metric on primary medication non-adherence endorsed by the Pharmacy Quality Alliance in November 2013. This white paper reflects information and opinions offered by a working group assembled by the NACDS Foundation, the Pharmacy Quality Alliance, and NEHI in May 2014.*

***The late former U.S. Surgeon General C. Everett Koop famously remarked that “drugs don’t work in patients who don’t take them.”***

***Dr. Koop might have continued this way: “Drugs never work in patients who don’t take them for the very first time.”***

**Introduction**

Primary medication non-adherence (PMN) is the term used to describe the situation when a patient is prescribed a medication for the first time but fails to obtain and take the medication, for whatever reason. Over the last decade the growth of electronic prescribing has enabled researchers to make more precise estimates of primary medication non-adherence, and the estimates are sobering, to say the least: PMN rates for many medications commonly used to treat familiar chronic illnesses range from 10 to 15 to 20 and even 30 percent.<sup>i</sup>

Unfortunately, primary medication non-adherence goes largely unaddressed in the U.S. health care system. Current initiatives to improve overall patient medication adherence, such as efforts by Medicare drug plans to improve adherence in order to improve their Star (quality) ratings, are evaluated by measures of Proportion of

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Days covered (PDC), a measure that reports on the percentage of a patient population that persists in securing its prescribed medications over time (a measure now generally benchmarked at the proportion of patients that have appropriate medication on hand for over 80 percent of the period evaluated). The current PDC measures are measures that are triggered by primary adherence – that is when patients pick up their medication successfully the first time. The high rate of primary medication non-adherence measured by researchers suggests that poor rates of adherence, as measured by PDCs, are in fact masking an even bigger problem.

In 2013, the Pharmacy Quality Alliance and its constituent organizations took a first step toward creation of formal quality improvement measurement that can be targeted at primary medication non-adherence, and create a foundation for PMN interventions that are scalable throughout the health care system. Specifically, PQA developed and endorsed an initial PMN quality measure that is designed for use among community pharmacies. PQA also is in the process of developing a parallel measure for use among health insurers and pharmacy benefit managers (PBMs) is also in development.

This issue brief will outline some of the most critical issues that health care stakeholders now face in operationalizing the new PQA measure on primary medication non-adherence across the care continuum.

## **Background**

Metrics of health care quality play an increasingly prominent role in U.S. health care. Initiatives for practice transformation and many health care payment reforms are linked to performance benchmarks that are created by accreditation or standards development bodies, such as the National Committee on Quality Assurance (NCQA), and URAC, and submitted for endorsement to the National Quality Forum (NQF).

Founded in 2006, the Pharmacy Quality Alliance is a member-based organization that convenes key stakeholders (including provider, payer, and pharmacy organizations) in consensus development of new quality measures that pertain to effective use of medicines, including measures of patient medication adherence. Like other quality measurement bodies, the PQA must approach development of new measures by considering both the clinical justification for a new measure, and the feasibility of collecting and reporting data on the measure on a recurring basis in the field. In 2013, the PQA developed and endorsed its new primary medication non-adherence measure in large part because electronic prescribing in the U.S. had reached a tipping point.

### ***Rapid Growth in Electronic Prescribing Creates a New Capability to Track Primary Medication Non-Adherence***

Until recently, the vast majority of prescriptions were communicated to the pharmacy on paper, most often by patients themselves. If a patient somehow failed to bring a prescription to the pharmacist, there was little a pharmacist or pharmacy could do to encourage the patient to fill the prescription

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unless the pharmacist had some way of knowing, or guessing, that a customer was overdue to fill a new prescription. There was no automatic or recurring way to track the “first fill” of newly prescribed medications and thus to calculate rates of primary medication non-adherence.

Electronic prescribing now makes it feasible to track “first fills” of newly prescribed medications and to calculate rates of primary medication non-adherence. When doctors and similarly equipped professionals “e-prescribe” a medication, they send authorization for a new prescription directly to the pharmacist; barring human error and technical glitches, 100 percent of e-prescribed prescriptions reach the pharmacist. Rates of PMN can be calculated by matching data on prescriptions that are received electronically with data on prescriptions that are actually dispensed and sold to patients. Both sources of data are owned by and accessible to the dispensing pharmacies (or to the chain or pharmacy network to which they belong.)

As of mid-2014, the vast majority of U.S. pharmacies are equipped to receive e-prescriptions, and the proportion of prescribers (physician practices, hospitals, other settings) similarly equipped is rapidly catching up. According to Surescripts, the dominant national e-prescribing network, 92 percent of community pharmacies in the U.S. participated in e-prescribing by year end 2013, and 73 percent of office-based physicians, up from 36 percent in 2010.

The proportion of prescriptions that are actually transmitted electronically lags the rate of adoption of e-prescribing capabilities by physicians and other prescribers. According to Surescripts t 58 percent of all eligible prescriptions were routed electronically in 2013, representing a 36 percent increase over 2012. This suggests that e there is much room for progress in e-prescribing (and thus for calculating rates of primary medication adherence for the majority of U.S. patients), but that e-prescribing is proving to be a relatively straightforward transaction that both prescribers and pharmacists are learning to master.<sup>ii</sup>

#### *E-Prescribing and Other Capabilities Found in Electronic Health Records May Engender a Natural Reduction in PMN - If EHRs Become Fully Functional*

Since widespread e-prescribing is still at this early stage, relatively little research has been done as yet to evaluate the impact of wide scale e-prescribing e on the adherence habits of large numbers of U.S. patients. There are reasons to believe that as increasingly higher proportions of prescriptions are processed electronically, a positive overall impact on patient adherence will ensue. Potential reasons range from the impact of added convenience for patients, caregivers and pharmacy customers, to the fact that electronically-received prescriptions are easily configured by pharmacies to trigger patient notifications through live pharmacist calls, central call center outreach, Interactive Voice Recognition (IVR) calls, and other means. Thus far research on the impact of automated outreach tends to show minimal impact on patient adherence, but further research under current conditions, when over half of all U.S. prescriptions are e-prescribed, may tell a different story.

Other, related “e-health” capabilities may provide a further lift to overall rates of patient medication adherence. In April 2014, the Office of the National Coordinator (ONC) reported that 73 percent of all

physicians now e-prescribing are doing so through e-prescribing functions embedded in an electronic health record (EHR). Many of the Meaningful Use (MU) objectives promulgated by ONC for providers seeking to attest to their EHR use are objectives that directly support effective medication management, and thus support improved patient adherence implicitly, if not directly. These include objectives for maintaining accurate patient medication lists, and access to formulary information that enables prescribers to prescribe drugs on-formulary and thus minimize out of pocket costs to patients. However, unlike the growing facility of prescribers with simple e-prescribing, the ability of providers to accelerate use of these other capabilities has proven difficult and has prompted continued calls for ONC to slow down the implementation of its Stage II Meaningful Use (MU) program. Continued delays in reaching widespread, effective use of EHR capabilities will inevitably inhibit any direct or indirect improvement effect that e-prescribing will have on primary medication non-adherence. For example, research on PMN by Dr. Michael Fischer and colleagues at Harvard Medical School has demonstrated that increased out-of-pocket cost to patients tends to increase primary medication non-adherence.<sup>iii</sup>

### **How the New Pharmacy Quality Alliance Measure on Primary Medication Non-Adherence Works**

#### ***Primary Medication Non-Adherence Defined***

The PQA measure on PMN defines “newly initiated” medication therapy as a medication prescribed for a patient who has not been prescribed the same medication within the previous 180 days. Patients are deemed non-adherent if they do not pick up their new prescription from the pharmacy within 30 days of receipt of the prescription by the pharmacy.

As previously noted, the initial PQA measure on PMN is designed for use by community pharmacies. Thus calculation of the measure depends on two sources of data that are within the control or ownership of community pharmacies: e-prescriptions received, and records of medications directly sold to customers. Since patients are free to purchase their medications wherever they wish (or wherever they can afford to purchase), it is of course possible that patients may appear to be “newly initiated” to a pharmacy calculating its PMN rate, but in fact may have purchased targeted medications at a different pharmacy within the prior 180 days, in which case pharmacies and other stakeholders (health plans, prescription drug plans, providers) may end up targeting PMN interventions toward patients who are not truly “newly initiated.”

Primary medication non-adherence should be distinguished from prescription abandonment. Prescription abandonment occurs whenever a prescription is filled by the pharmacy and not claimed by the patient, whether or not the prescription is new or a re-fill. Prescriptions that are abandoned and returned-to-stock include newly-prescribed, re-filled and re-prescribed medications.

A detailed outline of the PMN measure and its definition can be found in Appendix A.

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### ***Medications Subject to the New PMN Measure***

The new PQA measure on primary medication non-adherence is not directed at all patients nor all newly-prescribed drugs. The measure applies to a list of medications that largely parallels the chronic medications already subject to existing PQA metrics on patient medication non-adherence, the same metrics that have been incorporated into the Star ratings of Medicare Prescription Drug Plans and Medicare Advantage Prescription Drug Plans. Medications subject to the PMN measure include statin drugs for cholesterol control, anti-hypertension drugs, and oral diabetes medications. The new PMN measure also applies to the use of COPD medications and asthma medications. The overall list aligns very closely with the quality goals for chronic care management that are most commonly incorporated within the Accountable Care Organization contracts, contracting requirements from Medicare and commercial health plans relative to reduction of preventable hospital readmissions, and other performance-based payment innovations now found throughout the U.S. The measure does not apply to “fill if needed” or to PRN (“take if needed”) prescriptions, but to prescriptions likely to be taken on a maintenance basis by patients with chronic illness or chronic needs.

### ***The PMN measure is designed to be reported as a population-wide score***

As with the existing PQA metrics now used in the Medicare Star ratings, the PMN measure is designed to yield a score for the first-fill performance of groups of patients, from the larger patient populations defined by entire pharmacy chains or entire Accountable Care Organizations, to groups of patients (pharmacy customers) attributed to specific community pharmacy store locations. Unlike the existing PQA adherence metrics, which compare medication adherence against a benchmark of basic clinical effectiveness and health care quality (patients at or above 80 percent of Proportion of Days Covered by medication in the patients’ possession), the PMN score is a simple report of the proportion of patients who did not receive their newly-initiated prescription within 30 days of receipt of the prescription by the dispensing pharmacy. While the PMN measure is not explicitly designed to prompt reporting of PMN on a patient-by-patient basis, effective interventions to reduce PMN may well require providers or pharmacies to track the primary medication adherence of individual patients through “fill status” reported to the prescriber or the prescriber’s organization, to persons managing PMN quality improvement on behalf of the pharmacy, to similar persons working from within the health insurer or prescription drug insurance plan, or to partnerships representing some or all of these stakeholders.

### ***The PMN measure aligns with new priorities for Population Health Management***

As a measure of primary medication non-adherence across patient populations, the PQA measure on PMN is consistent with the focus on population health management that is characteristic of many current payment innovations (such as Accountable Care) and initiatives for health care practice transformation (such as the Patient Centered Medical Home model of primary care physician practice). Thus adoption of the PMN measure in practice could well hinge on whether payers and providers find common ground in linking improvement of patient PMN to the larger set of health care quality goals around which they are configuring payment reform, including payments tied to population-wide improvement in diabetes care and cardiovascular health care.

## **Reducing PMN: Should Pharmacies Take the Lead?**

The community pharmacy industry could act on its own to track primary medication non-adherence in accordance with the new Pharmacy Quality Alliance PMN measure. It can do so by comparing data from the e-prescription orders it receives from prescribers to data it compiles at the point of sale on prescriptions actually purchased by customers. Indeed many community pharmacists and community pharmacy organizations already do intervene to reduce primary medication non-adherence. E-prescriptions trigger outreach by pharmacies and pharmacies through live calls, automated calls and other communications.

However, the evidence on the effectiveness of this outreach is inconclusive at best. Community pharmacies face the same set of questions that confront all stakeholders as they consider ways to improve overall patient medication adherence: how much new investment in new tools, new processes, and new skills are necessary to achieve significant gains in adherence, and which patients, if any, should be targeted?

The pharmacy sector does not currently enjoy advantages and incentives enjoyed by other stakeholders with a potential interest in closing the PMN gap. Community-based pharmacists and community pharmacies are not part of the federal Meaningful Use (MU) program that provides financial and technical assistance incentives to physicians for adoption and utilization of electronic health records. To be sure the MU program as it currently exists, without pharmacist involvement, faces serious challenges, including physician complaints that the pace of MU mandates from the government is too fast, while achievement of EHR interoperability is too slow. Yet despite these problems physician e-prescribing has grown very rapidly with Stage One (now complete) of the MU program. The exclusion of the pharmacy sector from the program suggests that opportunities to nurture related capabilities, such as fill status notification to prescribers, may have been inhibited.

As of yet there has been relatively little direct reimbursement to pharmacies for action to reduce patient medication non-adherence, including primary non-adherence. Pharmacies are rarely empowered legally and operationally to bill directly for these services. There has been relatively little effort to incorporate community pharmacy services within new payment channels such as shared risk, shared savings, or pay-for-performance plans, although this could change rapidly as payment models that focus on total costs of patient care gain ground.

Nevertheless, there appears to be growing upside potential for community pharmacies in strategies to reduce primary medication non-adherence, starting with the potential to generate new sales and to reduce return-to-stock costs that occur when prescriptions are ordered but not picked up and sold. Community pharmacies also participate in the pharmacy networks that operate under contract with the Medicare Part D Drug Plans and Medicare Advantage plans that are, in turn, subject to Star rating quality measurement, including metrics of medication adherence. An increasing number of health plans and PBMs, including national-level payers such as Express Scripts and CVS Caremark (now CVS Health), are developing incentive and disincentive programs for their network pharmacies, with some payers

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electing to use a pay-for-performance structure to reward pharmacies that effectively contribute to quality goals around safe and appropriate medication use.

There is increasing reason to believe that the interests of community pharmacies, payers and providers are aligning around the need for improved medication management and patient medication adherence. Providers and payers are openly considering the advantages of integrating medical services with pharmacy services: if not the ownership of both, then the virtual integration or closer coordination of both. (See “Payment Innovations That Target Total Medical Expenditure or Total Cost of Care,” below.) Thus there is a growing interest in the integration of medical and pharmacy management under new Accountable Care Organizations, and potential tightening of coordination of hospital and physician services paid under Medicare Parts A and B with Medicare drug benefits paid for under Medicare Part D. Such integration could make PMN reduction a higher priority and open new avenues for partnership among the pharmacy sector, health care providers and traditional health insurers and other payers.

### **Operational Issues Confronting Stakeholders**

Assuming that key stakeholders do find their interests aligning around the need for improved patient medication adherence, adoption of the PMN measure will require a shared vision of the interventions and new investments likely necessary to reduce PMN – regardless of which stakeholder is ultimately responsible. The question for all stakeholders is: PMN can be monitored, but can it be effectively reduced?

Major operational issues include:

### ***Dashboards and Actionable Intelligence***

As noted, the PQA measure on primary medication non-adherence is designed to yield a population-wide score, such as “x percentage of patients using Community Pharmacy A were non-adherent to newly initiated therapy in the last year.” But data on PMN can be presented in a variety of ways. Stakeholders will need to compare and contrast options that offer data in ways that best trigger interventions that meld seamlessly within daily workflows, be they workflows in the physician practice, the community pharmacy or other settings (such as call centers that may deliver PMN interventions). Options could range from notifications of PMN status on single patients (see “Fill Status Notification,” below), to population-wide or other group scores that stakeholders can use to gauge their success in implementing interventions across entire groups of patients, (See “Best Practices on PMN Interventions,” below).

Adoption of the existing PQA metrics on medication adherence has already inspired work to create dashboard-style tools, delivered as web-based programs or through electronic medical records. One effort is from a direct PQA spin-off, Pharmacy Quality Solutions, which launched nationwide in 2013 and now serves more than 50,000 pharmacies nationwide. The EQuIPP tool provides pharmacists at the store level with a dashboard read-out of the adherence performance of patients who patronize these stores. EQuIPP is now tracking more than 15 million Medicare Part D drug plan enrollees.



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Experts generally agree that technical specifications to incorporate PMN statistics into tools such as EQuIPP are mostly in place already. Incorporation of PMN data into these tools will require an active commitment on the part of at least some pharmacy organizations to collaborate with tool developers in the design of the PMN functionality and to feed PMN-related data (e-prescription data, dispensing or fill status data) to tool developers. Once again, tighter coordination with efforts to deploy electronic health records and to accelerate prescriber use of medication-related capabilities beyond e-prescribing would accelerate the drive for effective PMN interventions among both prescribers and pharmacies. The Office of the National Coordinator (ONC), which administers the EHR Meaningful Use program, authorized to undertake such coordination, and coordination around closing the PMN gap would merit a high priority.

### ***Fill Status Notification***

As the name implies, fill status notifications are a notification indicating that a patient has or has not secured their prescription medication. Fill status data is used by dispensing pharmacies to trigger automatic outreach to customers, but there are no standard or formal procedures in U.S. health care regarding fill status notification to other parties, including prescribing physicians.

Fill status notification has an obvious clinical significance for initiation of new therapy by a patient: fill status notification would indicate whether the patient has really begun therapy. Given this clinical significance, some experts and healthcare IT advocates have called for inclusion of fill status notification in electronic medical records used by physicians and physician practices. Technical specifications are in place that would support inclusion of fill status notifications in active EHRs, but fill status notification is not currently an objective of the federal MU program. There appears to be little consensus in the physician community as to the comparative advantages of fill status notifications (a yes-or-no report on an individual patient secured their newly-initiated prescription medication) as opposed to access to more aggregated data (data on the PMN performance of entire categories of patients, or PMN rates for physicians), such as the dashboard-style data referenced above.

Given the increasing emphasis on population health management and chronic care coordination now evident in U.S. health care payment reform, the role of fill status notifications would seem to be more relevant than ever, and should prompt greater debate and discussion among physician, physician practice management, healthcare IT, pharmacy and payer leadership. It stands to reason to seek consensus on use of fill status notifications, the creation of dashboard-style tools and other sources of performance data and analytics will depend in many ways on consensus around best practices for interventions to reduce primary medication non-adherence.

### ***Best Practices on PMN Interventions***

There are no generally accepted practices regarding the type or sequencing of interventions that prescribers, payers and pharmacies, acting apart or together, should use to achieve lower rates of primary medication non-adherence.

Recent research on primary medication non-adherence has focused first and foremost on outreach to patients to inform or remind them that newly-prescribed medications are waiting for them to pick up at



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the pharmacy. However adherence research and practitioner experience long ago made clear that the reasons for PMN and other forms of non-adherence are much more diverse than simple forgetfulness. Interventions must be designed to identify and address multiple, patient-centered reasons for PMN. Recent studies supported by the NACDS Foundation and others tend to confirm that the timing of outreach (for example, how many days after receipt of the prescription outreach is initiated), the mode of outreach (outreach by live calls vs. IVR, etc.), and the source of outreach (from a local pharmacist or pharmacy assistant, from call center personnel, from the prescribing physician's office, etc.) are all decisive variables that influence whether the patient is likely to follow through and pick up medication.

The new PQA measure on primary medication non-adherence deems patients as non-adherent if they do not secure their prescription within 30 days of pharmacy's receipt of the prescription. This represents a generous grace period for deployment of PMN interventions. Recent experiments and emerging industry practices all deploy interventions more quickly. Interventions deployed by CVS Health have demonstrated success through live telephone calls delivered seven days after receipt of the prescription, while similar interventions piloted within the Geisinger Health System showed less impact when delivered at Day 14.

The use of fill status notifications to physician practices, as well as other forms of formal or structured feedback from pharmacy to physician practices remains relatively unexplored outside the ranks of highly integrated health systems that operate their own pharmacy operations alongside their medical operations. Studies have shown that PMN rates vary widely among physicians. Physicians receiving a high volume of notifications of PMN (i.e. notifications of non-fills of newly prescribed medications) may be persuaded to change their approach to prescribing and counseling patients on the benefits of initiating medications.

Alignment of PMN interventions with current payment trends would probably dictate outreach to patients within one to two weeks following the initial prescription. For example, performance standards for patient centered medical homes (PCMH) generally call for physician practices to schedule follow-up appointments with patients newly discharged from hospitals in as little as two days after discharge. Readmissions penalties imposed on hospitals by Medicare and some private payers are pushing many hospitals to adopt models of post-acute or "transitional care," and many of those models also call for follow-up visits in the community to be scheduled anywhere from two to seven days post-discharge.

***Agreement on collecting PMN data, and on calculating and reporting PMN scores: who or what organization will be responsible?***

Finally, adoption of the PMN measure will depend upon agreement among key stakeholders as to which organization or set of organizations will be responsible for reporting PMN scores and the data collection and analysis necessary to generate reports. The existing PQA metrics on medication adherence were endorsed by the National Quality Forum before its formal inclusion into the Medicare Star Ratings, and have since been incorporated into the 2015 beta-measure set of the Quality Rating System that will now be applied to health plans competing on state and federally-run health insurance exchanges under terms of the Affordable Care Act. The PQA measure on primary medication adherence for use among

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community pharmacies could follow the same path, as could the parallel measure on PMN for health plans currently under development – assuming that this second measure wins endorsement from the PQA membership.

Uses of health care quality measures in performance assessment, and as benchmarks for reimbursement have evolved rapidly in recent years, along with other mandates and administrative requirements. Many stakeholder organizations now claim to be reluctant to adopt new metrics without a demonstration of serious need or demand.

### **Is There Real Demand for Action on Primary Medication Non-Adherence?**

The operational issues around PMN reduction beg the larger question of whether there is or will be sufficient market demand to support action. Evidence of poor patient medication adherence has been documented for decades, but serious policy to correct it has only firmed up over the last 10 to 15 years, particularly with enactment of the Medicare Part D prescription drug program and subsequent incorporation of PQA adherence metrics into Medicare's Star ratings program.

Reforms enacted under the Affordable Care Act have further quickened the pace. Given that the PQA measures have been incorporated only recently, it is still early to draw definitive conclusions regarding their impact. But the inclusion of PQA-endorsed adherence metrics into the Medicare Star ratings program, and the linkage of those metrics to performance incentives for Medicare Part D plans and Medicare Advantage prescription drug plans, have clearly hastened the development of new tools and methods to monitor patient medication adherence and to intervene with patients.

At least two more recent trends in U.S. health care represent opportunities that could draw stakeholders (payers, prescribers, and the pharmacy sector) together in demand for action on primary medication adherence.

### ***Care Transitions***

Reduction in preventable hospital readmissions is a major Medicare goal under the Affordable Care Act. More than 2,200 hospitals are facing Medicare reimbursement penalties for readmission rates that are deemed too high under Medicare regulation. Readmissions-related payment policies (penalties, performance bonuses, or both) are under active consideration among state Medicaid plans and commercial health plans. At the same time, high costs and over-reliance on post-acute care providers is now considered by some health analysts to be a major opportunity for future Medicare cost reductions.

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Medicare readmissions policy currently targets patients admitted with chronic heart failure, myocardial infarction and pneumonia; patients with COPD will also be targeted in 2015. These are categories of patients who are invariably discharged from the hospital with multiple prescription medication orders. Immediate and seamless medication therapy – starting with primary medication adherence – would

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seem to be a critical first step in ensuring that any readmissions that can be reasonably prevented, are prevented.

### ***Payment Innovations That Target Total Medical Expenditure or Total Cost of Care***

While fee-for-service remains the dominant mode of health care reimbursement by far in the U.S. health care system, health care providers are steadily moving into models of payment such as Accountable Care in which they bear some risk for control of patient medical costs. Many variations on the Accountable Care model also tie bonuses or premium payments to quality benchmarks that are either tied to numeric levels of cholesterol, blood pressure, and blood glucose in patients or to newer, more flexible measures that still presume appropriate and persistent medication use among patients with chronic conditions. The Medicare program is now working to harmonize multiple sets of health care quality measures in order to streamline reporting requirements imposed on physicians.<sup>v</sup> This work does not yet include harmonization of measure sets that include PQA measures of patient medication adherence. However the trend toward management of total medical expenditure, or total cost of care, still puts the need for effective use of medications and good patient medication adherence into much sharper relief for both providers and payers. Patients who are not well-prescribed and adherent to medications are less likely to avoid illness or the progression of illness, and are naturally at higher risk for medical complications and medical spending that could be avoided with medication therapy.

A growing body of statistical evidence affirms this relationship. A recent case in point is a study by University of Maryland Professor and former Medicare Payment Advisory Committee (MedPac) Bruce Stuart and colleagues that demonstrated that average per-patient/per month spending by Medicare beneficiaries can vary by hundreds of dollars over the course of two to three years, depending on the pattern patient medication adherence.<sup>vi</sup>

In this new payment environment, primary medication non-adherence, the failure to initiate medication therapy ordered by prescribers, looms as a fatal flaw. Here again, the PQA measure on primary medication non-adherence as currently formulated focuses on adherence to a series of drugs that are heavily used in the treatment of chronic conditions that are targets of nearly all ACO and similar payment innovations now seen in U.S. health care.

### **Call to Action**

Poor, uncoordinated medication management and patient adherence has been called the “blind spot of accountability” for the growing number of Accountable Care Organizations in the U.S., but it is a blind spot that surely afflicts the vast number of U.S. patients who are served outside the newly formed ACOs or outside very highly integrated health care systems.<sup>vii</sup> Poor rates of PMN are at the center of the blind spot.

Thus far providers, pharmacy organizations, health insurers and public policymakers have fashioned adherence policy around the clearest set of targets that could be monitored feasibly given existing management and information systems, with PDC (proportion-of-days-covered) as the current best method for measuring adherence to medications commonly used in the treatment of major chronic

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illnesses. As a result current medication adherence policy is largely targeted at patients who secure newly-prescribed therapies at least once. Obviously this is policy that leaves out patients who never secure newly-prescribed therapy at all.

Electronic prescribing data and a new round of research now confirm that there are a vast number of patients who fail to complete the crucial first step of securing their new medicines after a physician prescribes it for the first time.

Naturally, identifying the extent of a problem is not the same as identifying effective ways to solve it. The reasons for poor primary medication non-adherence are very complex and range from financial reasons (such as out of pocket costs that are too large for patients), to poor health literacy, to simple forgetfulness and more.

If experience thus far with existing medication adherence metrics is a guide, then a commitment among key stakeholder groups (such as payers, providers, and pharmacy organizations) to explore utilization of the new measure will catalyze a process in which stakeholders can start comparing feasible solutions to the potential benefits of utilization, including benefits measured in improved patient outcomes and appropriate control of overall health care costs. This is how stakeholders have responded to date to the introduction of adherence metrics through the Medicare Star ratings program and other initiatives.

### **Recommendations**

Commitment to exploring use of the new PMN measure should begin with a few concrete steps that key stakeholders must take, some on their own, some in collaborations among themselves. These steps might include:

1. Joint, cross-stakeholder meetings and conferences that will bring focused attention to the prevalence of primary medication non-adherence, and the importance of closing gaps in PMN in order to reach widely shared goals in U.S. health care: better patient outcomes, effective strategies for population health management, and achievement of total cost of care goals;
2. Health insurers, health plans and major health benefit purchasers should consider new operational strategies for closing PMN gaps through changes in benefit design and in their relationships with PBMs and community pharmacies. The ongoing process within the PQA to develop a PMN measure for health plans should serve to accelerate this process;
3. The physician sector should be challenged to accept PMN-related information, such as fill status notifications as an essential indicator of treatment success;
4. The physician sector in turn should challenge the pharmacy sector, healthcare IT developers and payers to develop ways to feed PMN data to physicians in forms that are truly actionable, are minimally disruptive to physician workflows, and support achievement of other goals of physician practice such as population health management goals;
5. The pharmacy industry should continue active experimentation with PMN interventions, including experimentation on effective modes of outreach to non-adherent patients, and the most effective sequencing of outreach to patients and caregivers;
6. Adherence researchers should embrace the new PMN measure and begin to treat it as a standard that will enhance comparability of studies on patient medication adherence;

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7. All stakeholders should continue to advocate for the funding of continued research that quantifies PMN and links PMN to patient outcomes and patient health care costs; and
  8. National quality improvement and quality measure organizations (such as NCQA, NQF, URAC and others) should be challenged to lay the groundwork for establishing the PMN measure as a fundamental health care quality indicator.

Few important problems in health care prove simple or easy to solve; reducing the unacceptably high rate of primary medication non-adherence is not likely to be an exception to this rule.

But some problems in health care –like medical errors and poor patient safety – are too pervasive and fundamental to ignore. Primary medication non-adherence deserves to be listed high on this list of fundamental problems.

To paraphrase the late Dr. Koop once more: What's the point of health care if not to make drugs work in patients who need them?

## Endnotes

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<sup>i</sup> Fischer MA, et al, Primary medication non-adherence: analysis of 195,930 electronic prescriptions, *J Gen Intern Med* 25(4):284-90

<sup>ii</sup> Surescripts 2013 National Progress Report and Safe Rx Rankings, <http://surescripts.com/news-center/national-progress-report-2013>

<sup>iii</sup> Fischer MA, et al, Trouble getting started: predictors of primary medication nonadherence, *American Journal of Medicine* (2011), 124, 1081.e9-1081.e22

<sup>iv</sup> Chandra A, et al Large increases in spending on post-acute care in Medicare point to the potential for cost savings in these settings, *Health Affairs*, 32, no.5 (2013):864-872

<sup>v</sup> The measure set used within the ACO Medicare Shared Savings Program (MSSP) is currently undergoing alignment with other important Medicare programs, such as the Physician Value-based Modifier, the Physician Quality Reporting System (PQRS), and Meaningful Use.

<sup>vi</sup> Stuart B, et al. Increasing Medicare Part D Enrollment In Medication Therapy Management Could Improve Health And Lower Costs. *Health Affairs*, July 2013 vol. 32,no. 7,1212-1220

<sup>vii</sup> Shrank W, et al. [“Correcting The Blind Spot In Accountability: The Role Of Pharmacy Care. Health Affairs Blog, June 25, 2014, http://healthaffairs.org/blog/2014/06/25/correcting-the-blind-spot-in-accountability-the-role-of-pharmacy-care/](http://healthaffairs.org/blog/2014/06/25/correcting-the-blind-spot-in-accountability-the-role-of-pharmacy-care/)

## Appendix A

### Primary Medication Non-adherence (PMN)

#### Description

The percentage of prescriptions for chronic medications (see list) e-prescribed by a prescriber and not obtained by the patient in the following 30 days.

This rate measures the level of primary medication non-adherence across a population of patients

*The unit of measure is a pharmacy or network of pharmacies. It is not intended for use by pharmacy benefit managers or health plans, as the data required is not available in administrative claims.*

#### Data Requirements

To calculate this measure, pharmacy prescription dispensing data must be available. The pharmacy prescription dispensing data must include a field for prescription origin or be linked to an e-prescribing system to identify e-prescriptions.

#### Definitions

**Primary Medication Non-adherence (PMN):** PMN occurs when a new medication is prescribed for a patient, but the patient does not obtain the medication, or appropriate alternative, within an acceptable period of time after it was prescribed.

**Recommended Measurement Period:** The measurement period of time is 12 months. This is the time where the prescription medication fill pattern is assessed. The 12 month measurement period will require 19 months of pharmacy prescription dispensing data, 6 months prior to the measurement period (pre-measurement period) and one month following the measurement period (post-measurement period).

**Alternate Measurement Period:** The measurement period of time is 5 months. This is the time where the prescription medication fill pattern is assessed. The 5 month measurement period will require 12 months of pharmacy prescription dispensing data, 6 months prior to the measurement period pre-measurement period) and one month following the measurement period (post-measurement period).

**Newly Initiated Drug Therapy:** A prescription where the same drug (generic equivalent) has not been filled during the prior 180 days.

**Appropriate Alternative Therapy:** A drug product that appears in the same sub-table as the product that was e-prescribed (e.g., if Benazapril/HCTZ was prescribed, the appropriate alternatives would include any product listed in Table A2).



## Eligible Population

**Ages:** 18 years and older as of the last day of the measurement period

**Measurement Period:** Any 12-month period or (alternate) any 5-month period

## Administrative Specification

**Denominator:** The number of e-prescriptions for newly initiated drug therapy for medications in Table A (Chronic Medications) during the measurement period and for the eligible population.

**Note:** Using e-prescribing data, identify and count all newly initiated prescriptions transmitted through an e-prescribing portal for any medication in Table A for the eligible population.

**Pharmacies reporting must have 30 or more e-prescriptions for newly initiated medications in the denominator**

### Exclusions:

1. Exclude any prescription in the Denominator where there is a prescription dispensing record in the preceding 180 days for the same drug
2. Exclude any OTC medication that is e-prescribed
3. Exclude duplicate medications, defined as any medication that has been e-prescribed twice in a 30-day period with no prescription fill in between the e-prescriptions

**Numerator:** The number of e-prescribing transactions in the denominator where there was no pharmacy dispensing event that matched the patient and the prescribed drug or appropriate alternative drug within 30 days following the e-prescribing event.

**Note:** If a prescription is reversed it is not considered as a dispensing event

**Table A: Chronic Medications for PMN**

### A1

Statin Medications			
• lovastatin	• fluvastatin	• pravastatin	• simvastatin
• rosuvastatin	• atorvastatin	• pitavastatin	
Statin Combination Products			
• niacin & lovastatin	• niacin & simvastatin	• ezetimibe & atorvastatin	• ezetimibe & simvastatin
• atorvastatin & amlodipine	• sitagliptin & simvastatin		

### A2

Direct Renin Inhibitor Medications
• aliskiren

ARB Medications			
• candesartan	• irbesartan	• olmesartan	• valsartan
• eprosartan	• losartan	• telmisartan	• azilsartan
ACE Inhibitor Medications			
• benazepril	• enalapril	• lisinopril	• perindopril
• captopril	• fosinopril	• moexipril	• quinapril
• ramipril	• trandolapril		
ACE Inhibitor Combination Products			
• amlodipine & benazepril	• enalapril & HCTZ	• lisinopril & HCTZ	• quinapril & HCTZ
• benazepril & HCTZ	• fosinopril & HCTZ	• moexipril & HCTZ	• trandolapril-verapamil HCL
• captopril & HCTZ			
ARB Combination Products			
• candesartan & HCTZ	• irbesartan & HCTZ	• olmesartan & HCTZ	• valsartan & HCTZ
• eprosartan & HCTZ	• losartan & HCTZ	• telmisartan & HCTZ	• amlodipine & valsartan
• telmisartan & amlodipine	• amlodipine & olmesartan	• aliskiren & valsartan	• amlodipine & valsartan & HCTZ
	• azilsartan & chlorthalidone	• olmesartan & amlodipine & HCTZ	
Direct Renin Inhibitor Combination Products			
• aliskiren & amlodipine	• aliskiren & amlodipine & HCTZ	• aliskiren & HCTZ	• aliskiren & valsartan

### A3

Biguanides	
• metformin	
Biguanide & Sulfonylurea Combination Products	
• glipizide & metformin	• glyburide & metformin
Biguanide & Thiazolidinedione Combination Products	
• rosiglitazone & metformin	• pioglitazone & metformin
Biguanide & Meglitinide Combinations	
• repaglinide & metformin	
Biguanide & DPP-IV Inhibitor Combinations	
• sitagliptin & metformin	
• saxagliptin & metformin SR	
• linagliptin & metformin	
• alogliptin & metformin	

### A4

Sulfonylureas	
• chlorpropamide	• glyburide
• glimepiride	• tolazamide
• glipizide	• tolbutamide
Sulfonylurea & Biguanide Combination Products	
• glipizide & metformin	• glyburide & metformin
Sulfonylurea & Thiazolidinedione Combination Products	
• rosiglitazone & glimepiride	• pioglitazone & glimepiride

### A5

Thiazolidinediones	
• pioglitazone	rosiglitazone
Thiazolidinedione & Biguanide Combination Products	
• rosiglitazone & metformin	• pioglitazone & metformin
Thiazolidinedione & Sulfonylurea Combination Products	
• rosiglitazone & glimepiride	• pioglitazone & glimepiride
Thiazolidinedione & DPP IV Combination Products	
• alogliptin & pioglitazone	•

**A6**

DPP-IV Inhibitors		
• sitagliptin	• saxagliptin	
• linagliptin	• alogliptin	
DPP-IV Inhibitor Combination Products		
• sitagliptin & metformin IR and SR	• sitagliptin & simvastatin	• alogliptin & metformin
• saxagliptin & metformin SR	• linagliptin & metformin	• alogliptin & pioglitazone

**A7**

Incretin Mimetic Agents	
• exenatide	• liraglutide

**A8**

Meglitinides		
• nateglinide	• repaglinide	• repaglinide & metformin

**A9**

COPD Medications		
• tiotropium	• ipratropium/albuterol	• ipratropium
• indacaterol	• roflumilast	• aclildinium bromide

**A10**

Inhaled Corticosteroids			
• beclomethasone	• fluticasone	• fluticasone & salmeterol	• triamcinolone
• budesonide		• mometasone	• budesonide & formoterol
• ciclesonide			• mometasone & formoterol

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