



# **BETTER USE OF MEDICINES FOR DIABETES PATIENTS**

5 CRITICAL WAYS TO IMPROVE CARE

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THE NETWORK FOR  
EXCELLENCE IN  
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# I. EXECUTIVE SUMMARY

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**T**ype 2 Diabetes has reached historically high levels in the United States and poses a major challenge to public health and health policy. Treatment of diabetes and related conditions is estimated to cost the U.S. health care system as much as \$322 billion per year and affect nearly 30 million people.<sup>1</sup> Diabetes also poses a special fiscal challenge to the nation, in that millions with diabetes are now, or will eventually be, covered by Medicare, Medicaid, or federally subsidized private coverage under the Affordable Care Act.

Some diabetes patients can manage their condition through proper diet and adequate physical activity, but many will end up on multiple medications and complex drug regimens that can test even the most capable patients. More than 4 in 5 of those actively treated for Type 2 diabetes use either oral medications, injected insulin, or both.

Patients face multiple obstacles in using these medications correctly, ranging from inadequate education and training to high out-of-pocket costs. Poor adherence often leads to worsening disease and avoidable costs. Estimates suggest that ensuring better use of medications among patients with diabetes could save \$4 billion annually in Medicare spending.

This paper describes five sets of challenges involving medications in diabetes care, and offers recommendations that could drive change. If providers, payers, and policy makers adopted these recommendations, the nation could take another major step toward achieving the goals of Triple Aim: better health for Americans, better care, and more sustainable health spending trends.



## THE PROBLEMS

### 1 DISEASE COMPLEXITY

Diabetes is a complex condition that often leads to complex medication regimens. Underlying factors that can trigger Type 2 diabetes, such as obesity, may also lead to other conditions such as hypertension, heart disease, and depression. Patients' multiple medications can include two different forms of insulin, which they may have to inject themselves, as well as drugs to lower blood pressure and cholesterol. Doses may have to be adjusted frequently by clinicians and patients often self-adjust insulin based on their blood sugar levels. In addition, there is an overall trend toward "intensification" of treatment to tighten blood sugar control that is leading higher doses of medication for more patients. .

## 2 FRAGMENTATION AND LACK OF CONTINUITY OF CARE

Achieving the best results with medications for diabetes patients requires thousands of steps every year, not only from patients, but also from clinicians, pharmacists, and payers. Success requires a high degree of coordination and support, but many patients experience fragmented and uncoordinated care. Many factors common to the U.S. health system foster poor results: multiple and uncoordinated prescribers, gaps in communication of patients' data, and failure to track patient adherence.

## 3 UNEVEN ACCOUNTABILITY FOR QUALITY

Pharmacy quality goals, or measures, applied to programs like Medicare have helped to spur better follow-up with patients and have raised patients' adherence. But gaps in these quality goals remain, such as the lack of an accepted measure of patient adherence to the use of insulin products.

## 4 CHALLENGES IN PATIENT SELF-MANAGEMENT

Patients with diabetes must invest substantial personal time and effort every day to maintain optimal control of their condition. Challenges include understanding how to properly administer insulin products, recognizing and acting on episodes of low blood sugar, and coping with other risks. Support for patients' self-management education and training has been shown to help, but only about 2 in 5 patients on average say they have ever received such support.

## 5 COST BURDEN ON PATIENTS AND PAYERS

For many patients with diabetes, the high cost of medications is a major contributor to poor adherence. Spending on diabetes-related drugs has risen for both patients and payers due to the trend toward intensified treatment, a decade-long trend in higher prices for insulin products, and to date, a lack of a generic insulin equivalent. The trend towards health insurance plans with higher patient deductibles and other cost-sharing feature also reduces patient adherence to medications.

## THE SOLUTIONS

### 1 TAILOR MEDICATION MANAGEMENT STRATEGIES TO PATIENT NEEDS

Medication-related services including so-called Medication Therapy Management (MTM) – special care provided by pharmacists to optimize drug therapy – should be customized to meet the complex needs of individual patients. The Medicare program's "Enhanced MTM" pilot program, scheduled for launch in 2017, is a promising strategy that should be rapidly evaluated for best practices that can be scaled up throughout the health care system.

## 2 REDUCE FRAGMENTATION IN MEDICATION CARE

Advances such as the rapid uptake of electronic prescribing are improving continuity of medication care for all patients, but much more needs to be done for those with diabetes. Medicare as well as private payers and health systems need to transfer adherence data into the hands of prescribers to facilitate quick problem resolution. Medicare should take the lead in allowing pharmacists to bill for identifying and resolving patients' specific drug therapy problems and adopt new billing codes to make that possible. States and others need to expand the use of so-called collaborative practice agreements, which allow physicians, nurse practitioners and other prescribers to delegate authority for medication-related care to pharmacists and other qualified professionals.

## 3 CLOSE GAPS IN PHARMACY QUALITY IMPROVEMENT

Medicare, Medicaid, and private health plans should adopt a more comprehensive set of improvement goals aimed at diabetes and medication use. The targets should include driving down "primary" medication non-adherence -- which is when patients fail to fill their first dose of a prescription -- and creating a measure to capture adherence to insulin.

## 4 OPTIMIZE PATIENT SELF MANAGEMENT

Medicare, Medicaid, and commercial health plans should reduce cost barriers that may prevent patients from enrolling in diabetes self-management education and training. They should also encourage innovative delivery of patient support, such as diabetes education and training delivered through patient visits at retail pharmacies.

## 5 CUT COSTS TO PATIENTS AND PAYERS

After a decade-long runup, prices of some insulin products have decreased recently, and the introduction of biosimilar insulins in coming years may moderate costs further. Patients have also benefited from relatively low prices on oral diabetes drugs, many of which are generics. All stakeholders -- the Executive Branch, Congress, regulatory agencies, payers, pharmacy benefit managers and manufacturers -- should consider further steps to foster a strong competitive market that will help keep diabetes medications affordable. Meanwhile, health insurance and prescription drug benefits should be designed to lower copayments and other cost barriers faced by patients, as these depress adherence and lead to avoidable costs. Payers should experiment with broader adoption of value-based insurance designs (VBID) that support optimal use of medications and lead to lower health costs.

# OPTIMIZING MEDICATION USE FOR DIABETES PATIENTS

## 5 CHALLENGES, 5 SOLUTIONS



### THE PROBLEMS

the disease is  
**COMPLEX**

Managing diabetes is complex as is the disease and the medication use. This complexity can lead to poor outcomes and avoidable costs.

medication care is  
**FRAGMENTED**

From primary care provider, to specialist, to pharmacist information is often either not shared or able to be shared. This fragmentation can lead to poor adherence.

accountability uneven for  
**QUALITY**

Medication adherence rates in diabetes are low. Payers and providers are not incentivized to address the problem, especially in the use of injectable insulin.

patient  
**MANAGEMENT**

Patients must be involved in the every day process of managing of their diabetes and blood sugar with medication, diet and exercise.

patients carry  
**COST BURDENS**

Out of pocket costs for patients can be high due to the design of their benefit plans and because of rising costs of insulin. These costs alone can result in poor adherence.

### THE SOLUTIONS

tailor  
**MEDICATION INTERVENTIONS**

Enhanced medication services (such as medication therapy management), should target the patients that need them most.

create continuity in  
**MEDICATION CARE**

Better coordination among patients, providers, payers and pharmacy should include sharing data on prescriptions and resolving problems across care teams.

close gaps in  
**QUALITY IMPROVEMENT**

For oral medications, performance on existing quality metrics (e.g. Medicare Star Ratings) must be improved upon. An effective, operational metric for insulin must be developed and validated.

optimize  
**PATIENT SELF-MANAGEMENT**

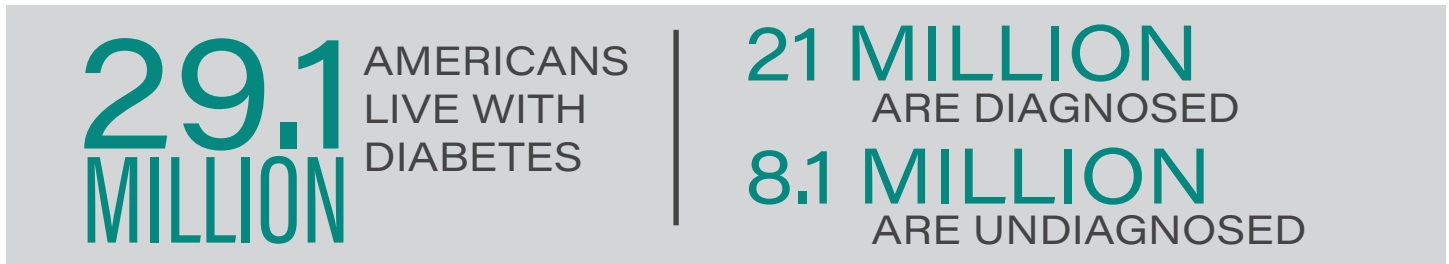
Cost barriers facing patients should be lowered for Diabetes Self-Management Education and Training or DSME/T. Training should also be expanded to sites such as retail pharmacies.

cut costs to  
**PAYERS and PATIENTS**

The design of benefits should be diabetes-friendly, reducing out-of-pocket costs that impede patient medication adherence. All stakeholders should consider steps to foster a strong competitive market for diabetes medication.

## II. BACKGROUND

**D**iabetes has risen to record levels both globally and in the United States. In recent decades, the U.S. has witnessed a 400 percent increase in diagnosed cases of diabetes, from 5.5 million in 1980 to 22 million in 2014.<sup>2</sup> Nearly one in ten Americans lives with diabetes,<sup>3</sup> whether diagnosed or undiagnosed. More than one in three adults has prediabetes,<sup>4</sup> a condition that, if left unchecked, can progress to type 2 diabetes. Nearly 26 percent of U.S. residents aged 65 or older (of Medicare age) are estimated to have diabetes.

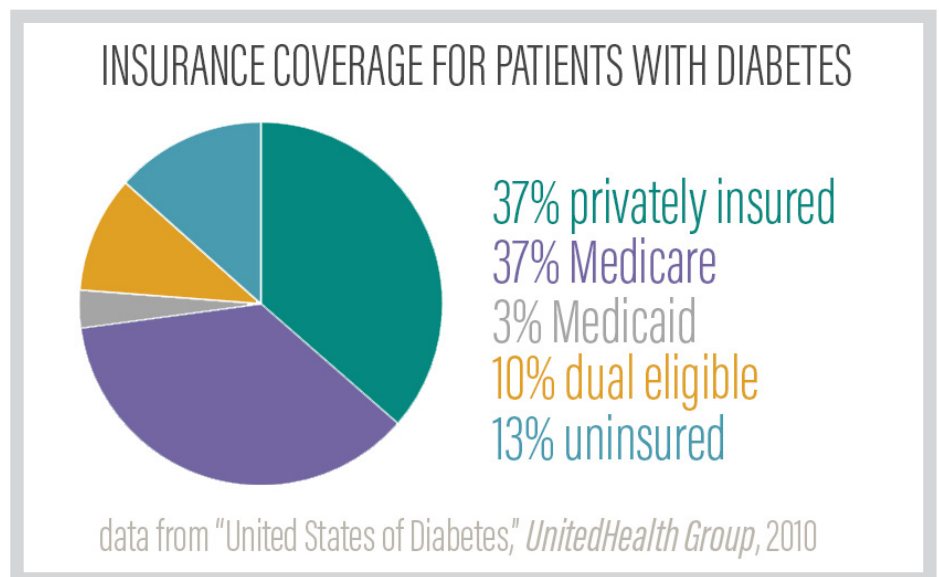


### The Toll on Patients

**D**iabetes can be controlled to varying degrees through lifestyle modifications and medicine, but uncontrolled diabetes can result in heart attacks, strokes, vision problems and blindness, kidney disease, nerve damage, and death. In 2010, an estimated 73,000 amputations of lower-extremities – toes, feet, and legs – were performed due to diabetes; and in 2011, 44 percent of all newly diagnosed cases of kidney failure were attributed to diabetes.<sup>5</sup> Diabetes is listed on death certificates as the 7th leading cause of death in the U.S., although the likely contribution of diabetes to overall mortality is almost certainly higher, given the co-morbidities that many patients suffer. Progressive diabetes is often associated with heart disease, the leading cause of death in the U.S. Patients diagnosed with diabetes have nearly twice the risk of death from cardiovascular disease compared to the rest of the U.S. population.<sup>6</sup>

### The Cost to the Health Care System

**T**he costs of caring for Americans with diabetes are substantial. On average, medical expenditures for people diagnosed with diabetes are 2.3 times higher than for patients without diabetes.<sup>7</sup> As the prevalence of diagnosed diabetes increases, so too do the costs. Both direct medical costs of diabetes, and indirect costs associated with disability, lost productivity, and early death, increased 41 percent from 2007 to 2012, rising from \$174 billion

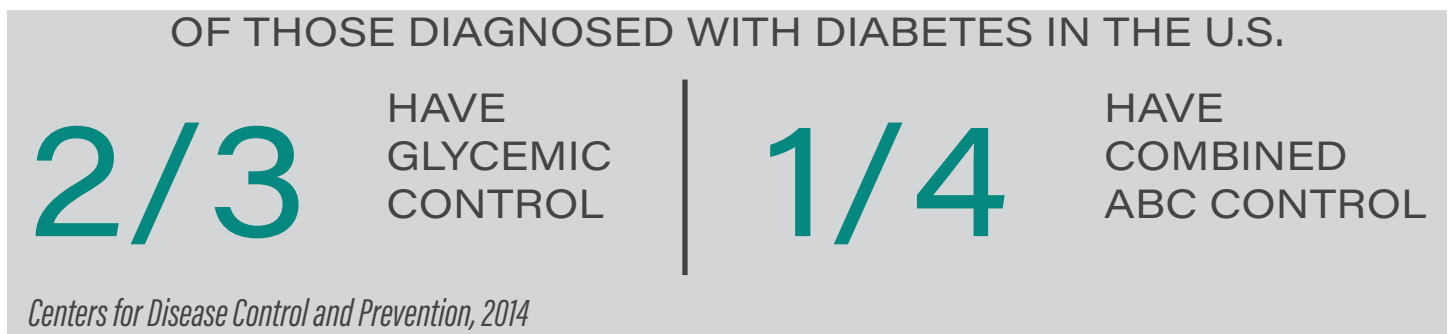


to \$245 billion annually.<sup>8</sup>

The human and financial costs of diabetes imposes a particular burden on public spending at both the state and federal levels. More than half of the patients diagnosed with diabetes are covered by Medicare or Medicaid.<sup>9</sup> In addition, more than one-quarter of the Americans living with diabetes are 65 years or older, and thus of Medicare age. This population constitutes more than \$100 billion of the nation's spending on diabetes. One in every three dollars spent on Medicare pays for diabetes-related medical costs.<sup>10</sup>

## Widespread Gaps in Care

**R**esearch and clinical practice have demonstrated that effective diabetes care can control the condition and mitigate complications, lowering lifetime costs of care and reducing hospitalizations, among other interventions.<sup>11</sup> But large numbers of people diagnosed with diabetes fail either to receive needed treatment or to stay in treatment over the long haul.



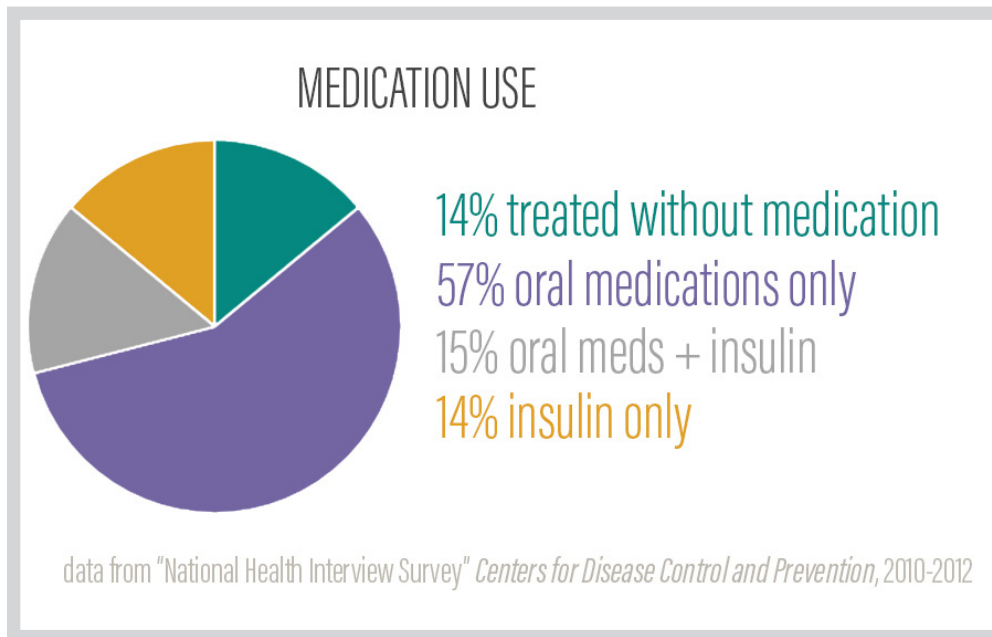
A common measure for determining whether a patient's diabetes is under control is "A-B-C." The "A" stands for adequate control of hemoglobin A1c, an indicator of blood sugar levels that helps to determine whether treatment is working. The "B" stands for blood pressure, and "C" for cholesterol – two measures of cardiovascular health that reflect the fact that heart disease is the most common and rapidly occurring complication of Type 2 diabetes. Overall, the CDC estimates indicated that just over a quarter of patients with diagnosed diabetes had good control of their A-B-Cs.

The Combination of good nutrition and daily physical exercise is a cornerstone of evidence-based treatment for persons with diabetes from its earliest to the most-advanced stage. In fact, the groundbreaking Diabetes Prevention Program (DPP), a large federally funded clinical trial, demonstrated that modest weight loss achieved through dietary changes and exercise can thwart progression of prediabetes – a condition marked by somewhat elevated blood glucose levels – to diabetes.<sup>12</sup> As a result, Medicare now covers a structured lifestyle intervention program based on the DPP that aims to help beneficiaries achieve a 5 percent weight loss.<sup>13</sup>

Once a patient's condition has progressed from prediabetes to diabetes, medications will almost certainly be necessary to maintain optimal blood sugar control. At that point, the patient will most likely need to use medications for the rest of his or her life, in addition to maintaining eating habits and daily physical activity that will keep blood glucose levels within a healthy range. And as previously described, this fundamental reality creates multiple challenges for patients and the health care system.

More than half of all patients treated for diabetes are treated with oral anti-diabetes medications

only, often starting with pills for metformin, a drug first discovered in 1922 and widely available in generic form. Even patients who eventually transition to injected insulin drugs will typically begin with metformin or other oral medications. There is a growing list of such oral medications, including those in the sulfonylureas, meglitinides, and DPP-4 drug classes, that provide alternatives to insulin or that can delay its use.



About 15 percent of patients actively treated for diabetes are prescribed insulin alongside oral medications. Insulin is either injected into the body as a shot, or via an insulin “pen;” alternatively, it can be infused into the body through a pump. Slightly fewer (about 14 percent) of patients are prescribed insulin only. Patients who are prescribed insulin typically have more advanced disease, and may include those who previously had no access to health care or did not otherwise receive timely care; patients

who previously were treated but then “lost to treatment” for various reasons; patients whose disease has progressed despite use of oral medications; or patients perceived to be at higher risk of uncontrolled hyperglycemia. Because of their advanced disease, as a group, patients using insulin are generally at higher risk for the onset of complications such as neuropathy, cardiovascular disease, and kidney disease.<sup>14</sup>

### III. THE PROBLEMS

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Clinicians define “optimal” medication use as encompassing several factors. For a patient with multiple chronic conditions, optimal use may include being prescribed safe and clinically-effective dosages of each medication needed to address the patient’s conditions (no “gaps in care”). In addition, the patient should not be prescribed drugs that are redundant – for example, when a second drug prescribed for a given condition provides no additional benefit over the first drug. The patient’s daily medication regimen also should be designed to maximize the odds that the patient will successfully obtain the drugs, adhere to them, and persist in appropriate daily use of the medications. Achieving these goals can reduce both the costs and the complexity of managing the regimen.

Attaining optimal medication use for diabetes patients is thus extremely challenging, and many patients’ drug regimens fall far short of this ideal state. Sub-optimal use of medications is undoubtedly a key reason that various measures, such as those reported by the National Committee on Quality Assurance’s Healthcare Effectiveness Data Information Set (HEDIS) program, still indicate widespread levels of poor control of diabetes.<sup>15</sup>

Simply put, the sub-optimal use of medications in diabetes care can lead to avoidable health complications and avoidable costs. IMS Health has estimated that, overall, sub-optimal use of medications



for patients with Type 2 Diabetes may lead to \$4 billion annually in avoidable Medicare spending. As a result, achieving diabetes medication use that is as close to optimal as possible is a critical objective for improving health and lowering total costs of care.<sup>16</sup>

Patients, caregivers, clinicians, payers, and pharmacists face a number of long-standing challenges to the optimization of medication use among persons with diabetes. One indicator is adherence rates.

With respect to use of oral diabetes medications, current adherence rates are poor – and no better than rates of adherence to other commonly used oral medications. An estimated 10 to 20 percent of patients fail to pick up a newly-prescribed dose of medication (primary medication non-adherence). Of patients who do obtain their initial prescriptions, only 65 to 85 percent of patients have medication on hand at least 80 percent of the time (a measure of known as proportion-of-days-covered, or PDC).<sup>17</sup> And as many as one half of patients are apt to discontinue use of medications after approximately six months of use.

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*As many as one in five fail to pick up a newly prescribed dose of oral medication*

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Accurate, population-wide measurement of adherence to insulin is confounded by a number of factors that make measurement especially difficult (see section on accountability for quality below). Still, reported rates of patient adherence to insulin are consistent with the poor medication adherence rates in use of oral diabetes medications. Although most people with diabetes need two insulin shots daily – and some need three to four – published studies suggest that only about 65 percent of patients, whether new or long-term users, have insulin on hand at least 80 percent of the time.<sup>18</sup> And as many patients become less adherent to use of insulin and other medications over time, they are more apt to develop avoidable complications and incur higher total costs of care.<sup>19</sup>

Although some of these poor rates of adherence may be improving because of the growing use of e-prescribing, more work is needed to achieve optimal use of medications among patients with diabetes. Five broad factors characterize the problem, starting with the sheer complexity of diabetes itself.



## DISEASE COMPLEXITY

**A**s noted, many patients with diabetes take multiple medications, a situation that research shows can lead to sub-optimal outcomes and avoidable health care costs. In addition, patients must often take drugs in varying dosages, at varying points of the day, and through different means of administration (such as pill vs. injectable form). These regimen complexities are associated with higher rates of adverse drug events, unresolved drug therapy problems, avoidable hospitalizations, and excess hospital readmissions.<sup>20</sup> The complexities also pose special challenges for patients with relatively low levels of health literacy or

“patient activation,” often defined as the knowledge, skills and confidence a person has in managing his or her own health and health care.

Given that diabetes is a disease that affects metabolism — the fundamental ability to take in food and convert it into energy for the body — it can lead to the breakdown of the body’s other organ systems, including circulation. What’s more, the same underlying factors that can trigger diabetes, such as obesity, may also lead patients to develop other conditions, ranging from hypertension and heart disease to depression. These “co-morbidities” add another layer of complexity to the condition. An estimated 70 percent of patients with diabetes have at least one co-morbid condition, and 40 percent have at least three.<sup>21</sup> Estimates of the rate of co-morbid depression among patients with diabetes range as high as 30 percent.<sup>22</sup>

The frequency of co-morbid conditions increases as diabetes progresses or is left uncontrolled. A recent analysis by the Tufts Center for Evaluation of Value and Risk in Health based on clinical data from more than 160,000 patients identified 14 significant clusters of diabetes with combinations of co-morbid conditions, with patients prescribed a daily average of 4.9 oral medications.<sup>23</sup>

A DAILY AVERAGE OF

4.9

MEDICATIONS

As noted above, patients with diabetes are routinely screened for their “A-B-Cs:” hemoglobin A1c levels, blood pressure, and cholesterol. Patients are frequently co-prescribed statin and anti-hypertension medications along with metformin and other oral diabetes medications. Use of statins and anti-hypertensives among diabetic patients is crucial to long-term health, in that cardiovascular disease is frequently among the first disabling and life-threatening conditions faced by patients with uncontrolled or progressive diabetes. Yet historically, reported rates of adherence to these drugs are roughly comparable to the rates for oral diabetes medications. Adherence based on proportion-of-days covered, or PDC, ranges from 60-80 percent. It is common for patients to discontinue these medications outright after six months.<sup>24</sup>

## Insulin

Insulin use adds further layers of complexity to medication management among patients with diabetes, as follows:

- **Self-monitoring:** Patients using insulin are nearly always asked to routinely self-monitor their blood glucose levels through use of test strips and glucose monitors. Self-monitoring is particularly important as prescribers and patients adjust, or titrate, doses of insulin to achieve optimal control of the patient’s blood glucose levels.
- **Self-injection:** Patients must be trained to successfully self-inject insulin. In the U.S. most patients are directed to self-administer insulin by use of a syringe and a vial, so patients must learn to withdraw accurate doses from a vial. Many patients must also learn how to overcome fear and pain of using syringes routinely, as well as use of drawing blood through test strips. Studies have shown that up to a half of patients view the initiation of insulin as a mark of failure on their part, thus undermining their motivation to persist in treatment.<sup>25</sup>
- **Use of multiple insulin products:** Patients at more advanced stages of diabetes may require both a long-acting (basal) insulin and a short-acting (bolus) insulin that is taken with meals. Optimal use of basal and bolus insulin is a key factor in maintaining good patient health, as well as control of health care utilization and costs.

## Intensification and Transitions of Therapy

When lab results and patient monitoring indicate that a patient’s diabetes is poorly controlled, guidelines advise that patients and clinicians should move quickly to intensify treatment.<sup>26</sup> In practice, intensification often means increasing doses of previously-prescribed medications, adding new medications (including use of insulin), or both.<sup>27</sup>

Recently published analysis indicates that the units of insulin used per treated patients in the U.S. increased by 20 percent in a decade (2002 to 2013). Over the same period, units of oral medications per patient increased by 31 percent.<sup>28</sup>

Adding further complexity, there is a parallel trend towards “personalization” of treatment goals. Both clinical research and practice shows that “one size fits all” treatment goals aimed at lowering hemoglobin A1c to particular levels can be too tight for some patients — such as older patients at risk of hypoglycemia, or very low blood sugar — but are not tight enough for others. As a result, newly proposed Medicare physician payment incentives under the Quality Payment Program endorse standards for “individualized” glycemic treatment goals approved by diabetes specialty societies.<sup>29</sup>

Numerous studies have shown that as the sheer complexity of a patient’s medication regimen increases, so do the odds that the patient will make mistakes in using his or her medications, experience side effects, discontinue use of medications, and suffer avoidable complications.<sup>30</sup> “Regimen complexity” is not only defined by the number of drugs a patient takes (sometimes known as “polypharmacy”), but also by broader measures of just how complicated it is for a patient to maintain optimal use of his or her drugs. Thus medication regimen complexity itself is a major barrier to achieving optimal use of medications among patients with diabetes.<sup>31</sup>



## FRAGMENTATION AND LACK OF CONTINUITY OF CARE IN USE OF MEDICATIONS

**P**atients with diabetes often find that their complex medication regimens create complexities in day-to-day use of medications that pose significant barriers to long-term adherence and persistence, and thus to good health itself.

In a 2012 analysis published in the *Annals of Internal Medicine*, a Kaiser Permanente clinician and researcher, Dr. John Steiner, estimated that a hypothetical 65 year old patient following an “A-B-C” regimen of oral diabetes medications, statins, and anti-hypertensive medications, is responsible for more than 2,000 intentional, medication-related behaviors in a single year (and more than 3,000 if dietetically-appropriate meals are included.) The odds that a patient will navigate each step successfully over the course of a year is conditioned on a host of factors, including the patient’s response to therapy and potential side effects, the ongoing cost of medications to the patient, and the patient’s ability to self-manage over time. Steiner

described patient medication adherence as “a cluster of behaviors, not a single construct” in which the odds of a patient persisting with medication use at any point “downstream” of the point-of-prescription is influenced by a host of factors “upstream.”<sup>32</sup>

Thus, achieving optimal results for the patient using a complex medication regimen requires a high degree of coordination across multiple sectors of the health care system, and a high degree of coordination in support of the patient. The challenge is systemic, and extraordinarily complex.

A systematic review by the RAND Corporation of published literature on patient medication adherence identified four overarching ingredients of adherence: optimal prescribing of the right medication at the right time for the specific patient; fulfillment, which means that the patient secures and takes the medicine; persistence, or the patient taking the medicine for the prescribed period of time; and conformance, which means that the patient takes the medicine as intended each time.<sup>33</sup>

Optimal prescribing alone is itself highly complex. A 2006 Institute of Medicine analysis identified 14 separate, prescriber-related root causes of medication errors, each of which also contributes to medication use that is sub-optimal and likely to invite patient non-adherence.<sup>34</sup> Patient-related behaviors are responsible for an additional six root causes in the IOM analysis.

The challenge of ensuring good medication adherence and persistence is exacerbated when patients are treated by multiple physicians, each of whom is likely to prescribe medications. Current data is limited on the extent to which multiple prescribers treat patients with diabetes, but historical data on treatment of Medicare patients with multiple chronic conditions confirm that patients with multiple conditions are more likely than others to see multiple clinicians.<sup>35</sup>

Some studies have correlated an increasing number of prescribers with increased odds of adverse reactions to drugs and to higher utilization of medical care.<sup>36</sup> A recent analysis of care fragmentation stratified more than 500,000 commercial health insurance beneficiaries by the degree to which their care was dispersed across multiple providers in multiple settings. The analysis concluded that total costs of health care incurred by patients with diabetes varied by approximately 38 percent between patients with the lowest and the highest degrees of fragmented care.<sup>37</sup>

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Despite the fact that coordination of medication management has been one of several goals embraced by health care reforms and practice improvement initiatives over the last decade, improvements have been modest. The patient centered medical home (PCMH) model has emphasized the use of actively updated medication lists, among other interventions. Results on quality improvement in diabetes care among PCMH practices is mixed. HEDIS quality measurement program reports continued increases in preventive measures (such as screening patients for their hA1c levels) conducted by physicians, but fairly static results in outcomes. Fewer than 40 percent of patients covered by commercial and Medicaid health plans are reported to be in good control (hemoglobin A1c levels of less than 7 percent), while two-thirds or less of patients in commercial, Medicaid and Medicare plans are reported with hA1c levels of less than 8 percent, and 25 percent or more are reported in poor control (hA1c levels of over 9 percent).<sup>38</sup>



## INCONSISTENT ACCOUNTABILITY FOR QUALITY

**S**etting goals that health care providers and payers must achieve on behalf of entire populations or groups of patients is a strategy increasingly used in U.S. health care to improve health outcomes. When applied to use of medications, these goals are called “pharmacy quality” goals. In recent years, great strides have been made in applying such goals to Medicare, leading to improvements in adherence to medications commonly used in treating Type 2 diabetes. .

In 2012, for example, Medicare required Medicare Part D prescription drug plans and Medicare Advantage plans to report on medication use among beneficiaries. Plans must measure beneficiaries’ adherence to medications that control a patient A-B-Cs -- oral diabetes medications, blood pressure medications, and cholesterol medications. A patient is measured as adherent if, according to refill records, he or she has medication on hand at least 80 percent of the time – a measure known as 80 percent proportion of days covered, or PDC. Since 2012, CMS has also added several more measures of medication adherence, including a measure of statin use among patients with diabetes. .

These various measures are included as part of CMS’s five-star quality ratings system, which captures Medicare beneficiaries’ experience with their health plans and the health care system. Medicare Advantage and Part D plans are awarded from one to five Stars based on their performance across four major areas that track patients’ experience. One aspect that is tracked is medication safety and adherence. Within this measurement domain, A-B-C adherence is one of the most heavily weighted factors.

Because the star ratings go hand in hand with significant financial and other incentives for health plans, they have been a powerful spur to plans, and the pharmacies they work with, to improve patients’ medication adherence. Over the past five years, Part D prescription drug plans achieved higher medication adherence rates on average, though with some recent declines in their star ratings linked to adherence to oral diabetes medications. Medicare Advantage plans have achieved more continuous improvement in adherence rates to oral diabetes medications.<sup>39</sup>

The medication adherence metrics employed in Medicare have now been adopted in an increasing number of other health plans and pharmacy programs, including health plans offered on the state and federal insurance exchanges under the Affordable Care Act, as well as in some employer-sponsored health plans. CMS expects to introduce them into Medicaid managed care programs by 2020. Payers have also begun to extend these types of metrics to pharmacies..<sup>40</sup>

Despite the great importance of these measures, there are substantial gaps in pharmacy quality reporting that impact diabetes care, as noted above. These gaps include the following:

First, data on adherence to A-B-C’s, as measured by proportion of days covered, are skewed by the way this metric is calculated. Perhaps surprisingly, patients who fail to pick up a new medication the first time are not counted in these data, despite the fact that such patients may be at comparatively higher risk

for untreated conditions and poor health outcomes.<sup>41</sup> As a result, overall rates of adherence may appear better than they actually are.<sup>42</sup>

Second, there is a lack of an accepted measure of patient adherence to use of insulin products, in part because measuring adherence to insulin in a manner that is safe, clinically useful and operationally feasible is an extremely complex challenge. In part because a prescriber may instruct a patient to titrate insulin doses, a patient's use of insulin may be so variable from day to day that a simple measure that counts the number of insulin vials (or pre-filled pens) used has not been deemed valid as a safe and useful adherence metric.

The lack of a viable measure of insulin adherence is a serious omission in pharmacy quality goals. In effect, the absence of such a measure means that the adherence experience of patients who use insulin, and who are therefore at relatively high risk for medical complications and increased costs of health care, is not captured in the Medicare Star ratings, or in other performance measures that have begun to push patient medication adherence rates upward over the last decade. What's more, the lack of an insulin adherence measure also affects Star metrics for oral diabetes medications in a roundabout way: Patients using both oral diabetes medications and insulin are excluded from the calculation of adherence to oral medications. Largely as a result, up to 3 million Medicare beneficiaries with diabetes are omitted from measurement under the Star rating for use of oral diabetes medications, despite their higher risks for avoidable complications due to poor adherence.<sup>43</sup>



## CHALLENGES IN PATIENT SELF MANAGEMENT

**A**s noted above, patients with diabetes must invest substantial personal time and effort every day to maintain optimal control of their condition. Family members and other caregivers may shoulder a significant burden as well.

For patients with diabetes, the task of self-management begins with organizing one's daily diet and physical activity to maintain healthy blood glucose levels. Self-management of medications comes next, particularly for those patients who use insulin and must understand how to properly administer insulin products, how to recognize and act on episodes of hypoglycemia, and how to cope with other risks.

The burden of daily self-management has led to a growing body of research on how clinicians can identify patients who need assistance with self-management and on models of care that support assistance to patients.

Studies of two of these models, known as diabetes self-management engagement (DSME) and diabetes self-management education and training (DSME/T), show that patients who participate in them see slower progression of their diabetes, incur lower total costs of health care over time, and experience fewer hospitalizations and hospital readmissions.<sup>44</sup> DSME is primarily delivered in clinical settings such as physician practices, but positive results have also been demonstrated when DSME is delivered by qualified pharmacists in community pharmacies.<sup>45</sup>

Despite evidence of its clinical and cost effectiveness, utilization of DSME by clinicians and participation by patients is very limited. Recent surveys suggest that fewer than 60 percent of patients receive DSME at any point in their treatment, and only about 40 percent of patients self-report that they received diabetes education and training. In most cases patients are responsible for some share of DSME costs, which further inhibits participation in these programs.<sup>46</sup> Research also suggests that the impact of DSME can be limited unless patients receive periodic reinforcement through visits with diabetes educators or with their providers.



## COST BURDEN ON PATIENTS AND PAYERS

**O**verall medical and prescription drug spending on diabetes care is high. As previously noted, an estimated one third of Medicare spending is attributable to diabetes care, or approximately \$12,000 per capita annually for persons aged 65 or older. A recent analysis of employer-sponsored health insurance estimated that per capita spending on diabetes care for patients with employer-sponsored coverage is \$10,000 higher than per capita annual spending on patients without diabetes.<sup>47</sup> These high cumulative costs of care for persons with diabetes, both in medical outlays and prescription drug costs, have resulted in higher costs to payers, higher insurance premiums for all Americans, and higher out of pocket costs for patients.

One cost driver is the trend in clinical practice towards intensification of therapy – in effect, a trend to hold blood sugar levels under tighter degrees of control. A 2016 analysis of diabetes-related medication use among a nationally representative sample of patients suggests that the mean volume of insulin used per patient per year grew by about 20 percent over a decade (2002-2013), while the number of oral anti-glycemic medications (pills) per patient increased by 31 percent.<sup>48</sup>

A second driver is steeply rising prices for insulin — a drug first discovered in 1921 — which in effect have offset falling prices for oral diabetes medications. As of 2016, all insulin products used in the U.S. are branded products, although at least one generic form of insulin is likely to come onto the market soon. Between 2002 and 2013, the price of branded insulin products, measured in average price per milliliter, rose nearly 200 percent. Since 2013, the prices of some insulin products have declined; published estimates of price discounts won by insurers suggest that some payers have won substantial price concessions.<sup>49</sup> Meanwhile, in contrast, the prices of most non-insulin therapies generally fell over the same period. The mean price of metformin, which is available in both brand and generic forms, decreased by 93 percent over the decade, despite the fact that use of metformin grew rapidly during the same period.

As insurers, employers and consumers alike have struggled to manage health spending, one result has been a move to high-deductible health insurance plans, along with greater cost-sharing for consumers with respect to prescription drugs. The percentage of employees with high-deductible plans sponsored by employers has increased from 4 percent to about 25 percent in the last decade, according to Kaiser Family Foundation surveys, and nearly half of employees have a minimum general annual deductible of \$1000. About 90 percent of enrollees in the state and federal insurance marketplaces are in high-deductible plans.<sup>50</sup>

Approximately 80 percent of the least-expensive exchange plans (Bronze-level) require enrollees to pay a deductible before prescription drug coverage begins.<sup>51</sup>

High out-of-pocket costs for patients can have a significant impact on medication adherence. Rates of non-adherence related to costs are estimated to range between 14 and 30 percent.<sup>52</sup> When a patient's diabetes is left uncontrolled or poorly controlled, avoidable complications and costs can result over time. Research on commercial high-deductible insurance plans presented to the American Diabetes Association in 2016 found that patients with diabetes who are covered by high-deductible health insurance plans are prone to significant delays in treatment, resulting in markedly higher cumulative costs for treatment of diabetes complications.<sup>53</sup>

Other recent studies have demonstrated a similar dynamic among Medicare beneficiaries. Research presented to the American Diabetes Association in 2015 linked rising patient out-of-pocket costs to lower adherence (measured as proportion-of-days-covered) and to higher total costs of health care. Total costs of care (medical and pharmacy) per year for the least adherent 10 percent of patients were more than 95 percent higher than total costs for the most adherent 10 percent of patients.<sup>54</sup>

## IV. RECOMMENDATIONS

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### TAILOR MEDICATION MANAGEMENT TO PATIENT NEEDS

**A**s noted above, diabetes is a complex disease that is often treated with complex medication regimens that may be subject to frequent change as the disease progresses or as medications are adjusted. But population-level quality improvement goals, such as those included in pharmacy quality metrics, have been benchmarked to standard, “one size fits all” levels of glycemic control. Fortunately, these may be replaced in the years ahead by individualized glycemic control goals. If so, medication-related services including so-called Medication Therapy Management — care provided by pharmacists to optimize drug **therapy** and improve **therapeutic** outcomes — will need to be customized to meet the needs of the individual patient.

Key priorities for action include the following:

- **Target Chronically Ill Patients at Risk of Sub-Optimal Use of Medications:** Centers for Medicare and Medicaid (CMS) currently has specific eligibility standards that Medicare Part D sponsors must use to determine if patients are eligible for Medication Therapy Management (MTM) under Medicare. These standards have had the unintended effect of keeping use of MTM low, including among patients with diabetes.<sup>55</sup> CMS instead should link eligibility for MTM to signs that patients exhibit sub-optimal use of medications, including poor adherence and persistence. CMS should also experiment further with basing



eligibility standards on analytics that may predict future drug therapy problems for individual patients.<sup>56</sup> Congress should weigh these changes in eligibility standards as it considers reforms to Medicare chronic care policies and MTM.

- **“Right Size” Medication Services:** CMS has recognized the need to “right size” medication services by matching them to the intensity of needs felt by individual patients, especially patients with diabetes. An example is a planned seven-year pilot program for “Enhanced MTM” services that will be carried out by Medicare Part D drug plans in 11 states starting in 2017. The pilot is designed to test whether better matching MTM services to patient needs can help reduce net Medicare spending. Part D sponsors will receive special payment incentives, including performance payments, along with new regulatory flexibility, such as the ability to offer different MTM services to individual enrollees based on their level of medication-related risk. Part D plans also will be able to pay pharmacists differently, based on the varying level of health needs and complexity of medication regimens for different patients.

The Enhanced MTM pilot constitutes an important step forward in matching the services of pharmacists and other qualified professionals to diabetes patients’ complex needs. CMS should undertake rapid-cycle evaluations of the enhanced MTM program and apply lessons learned to all Part D plans, Medicare Advantage, and Medicaid, and disseminate them to commercial and employer-sponsored health plans as well.



## REDUCE FRAGMENTATION IN MEDICATION CARE

**T**he U.S. health care system is widely acknowledged to be fragmented, and patients with diabetes experience fragmentation first hand as they cope with the disease and their complex medication regimens. Despite recent advances, such as the dramatic upsurge in electronic prescribing, the U.S. as a whole has yet to achieve the “patient-centered, integrated medication-use system” that the Institute of Medicine (now the National Academy of Medicine) called for in a seminal 2006 report.

Some integrated systems such as Kaiser Permanente and Geisinger have developed important new care models to reduce fragmentation (see pages 22-23).

The imperative to improve diabetes care elsewhere could serve as an important force for driving more substantial systemic improvement in the use of medications. Needed steps include the following:

- CMS and the Office of the National Coordinator for Health Information Technology should continue to encourage use of health information technology and health data exchange to support optimal medication use. Most prescribing and even titrating of medication use by prescribers is still done without benefit of hard data on a patient’s actual adherence and persistence. Quality indicators linked to provider payments, as in the new Quality Payment Program under Medicare, should encourage providers to adopt such tools as computerized alerts signaling that patients have filled their prescriptions. CMS

should make eliminating patients' drug therapy problems an operational goal. Ensuring optimal use of medications includes identifying and resolving a patient's drug therapy problems, such as the need for adjustments in doses, responding to drug allergies, and other issues. To its credit, CMS has taken steps to develop billing codes that will support documentation and billing of medication reviews that solve drug therapy problems. These codes should be completed and made operational.<sup>57</sup>

- Health care delivery systems, payers, physician professional societies, and states should expand the use of collaborative practice agreements (CPAs). These arrangements allow physicians, nurse practitioners and other prescribers to delegate authority for medication-related care to qualified pharmacists and other professionals. Appropriate use of CPAs allows these expanded care teams to pro-actively identify drug therapy problems in specific patients and expedite resolution of problems. Currently 48 states authorize some form of CPAs, but the scope of existing CPA authority can be restricted either to pharmacists employed within the prescriber's organization (thus limiting the ability to use community-based pharmacist), or by restrictions on the scope of action allowed to the pharmacist or other professional.<sup>58</sup>



## CLOSE GAPS IN PHARMACY QUALITY IMPROVEMENT

**A**s noted above, pharmacy quality metrics first adopted by the Medicare program have helped boost medication adherence among Medicare beneficiaries. CMS and health plans should now address gaps in the performance of Medicare Advantage and Part D prescription drug plans, and adopt a more comprehensive set of improvement goals that will better address the complex risks faced by patients with diabetes.

- **CMS and its Part D and Medicare Advantage partners must work to reduce variations in Star ratings performance.** Only 32 percent of Medicare beneficiaries enrolled in Part D are in plans that are rated at 4 or more Stars (out of a possible five).<sup>59</sup> Lagging progress in adherence to oral diabetes medications is one reason and underscores the need for sustained progress.
- **CMS also should continue its transition to pharmacy quality assessment that emphasizes better use of medicines in diabetes care across all classes of medications.** One risk of setting population health or pharmacy quality goals that focus on a single class of medications – for example, the A-B-C's – is that it invites a “siloeed” response in which one health goal may be promoted at the expense of another. In 2017 Medicare will require the Part D prescription drug plans to begin reporting on a new measure of statin use among patients with diabetes. This data will be made public as a “display” measure, a step below incorporating it the Star ratings and thus linking it to performance incentives and penalties. This measure is a step towards a more balanced approach to managing medication use among patients with diabetes. Medicare should incorporate it into Star ratings, and apply it to Medicare Advantage, setting a precedent for adoption among health plans offered on the state and federal insurance exchanges.
- **CMS and other payers should adopt a measure of primary medication non-adherence.** Failure among diabetes patients to fill their first dose of a prescription is still not routinely tracked in the health care

system. Adopting a measure of primary medication non-adherence would compel tracking of these patients, and in turn, drive plans and health systems to grapple with the problem. Such a measure has been endorsed by the Pharmacy Quality Alliance for use by payers but remains unadopted.

- **Finally, CMS and other payers should develop and adopt an insulin adherence metric.** A comprehensive, population-based approach to improving use of medications among patients with diabetes will require valid measures of patients' use of insulin products. Recently the Pharmacy Quality Alliance convened a working group on this topic. The challenges to designing a safe, clinically useful and operationally feasible series of metrics are real, and may demand significant time and investment from stakeholder groups, but the effort should be a high priority for Medicare, Medicaid, other payers, and all stakeholders.



## OPTIMIZE PATIENT SELF MANAGEMENT

**E**vidence indicates that educated diabetes patients achieve better outcomes and have lower total costs of health care over time. Yet relatively few patients are exposed to validated models of diabetes self-management education and training (DSME/T). The challenge of activating and educating patients with diabetes will only grow as the number of patients with the disease grows in the U.S., and as active self-management, including the management of medication regimens, becomes more complex.

- **Medicare, Medicaid, and commercial health plans should reduce the cost barriers that deter patients from enrolling in diabetes self-management education and training.** Coverage of DSME through value-based health insurance design could help expand use of DSME in traditional clinical settings, such as physician offices, or in community-based settings such as retail pharmacies.
- **The retail pharmacy industry should also integrate DSME into its evolving operations model.** Community pharmacies are a promising venue for delivering these services, since patients make recurring trips to their pharmacy and could readily take advantage of education and self-management counseling there. A growing number of community pharmacies are experimenting with DSME alongside services such as Medication Therapy Management (MTM).<sup>60</sup> Other emerging industry practices, such as the “appointment based model” of patient visits with community pharmacies,<sup>61</sup> now offer an opportunity to reinforce what patients’ education and self-management skills. DSME instruction could also be incorporated into the Enhanced MTM model.



## CUT COSTS TO PAYERS AND PATIENTS

**V**arious cost pressures threaten optimal medication use by diabetes patients. Even as oral medication prices have dropped, insulin product prices have soared, adding to other forces that are raising overall health insurance premiums for Americans. In many forms of insurance, the growing costs of care, including for medications, are being shifted to patients in the form of higher co-pays and deductibles.

Given the huge burden of diabetes care on society, the economy, and the federal and state governments in particular, a much more competitive market in insulin products – and as a result, lower prices -- should be a major goal. Fortunately, two or more “biosimilar” insulins, or what are essentially generic forms of insulin, are likely to come onto the U.S. market in 2017, prompting competition that could contribute to lower costs. However, there is concern that price reductions for biosimilar insulins may be only 20 to 40 percent below branded insulin products — substantially lower than the reductions of 80 percent or greater for most small-molecule generics.<sup>62</sup> Multiple stakeholders, including Congress; federal regulatory agencies such as the Food and Drug Administration and Federal Trade Commission; pharmaceutical companies, and pharmacy benefit managers, should all watch developments closely, and take whatever steps may be necessary to assure that a robust competitive market in biosimilar insulins materializes.

**Meanwhile, payers, including commercial, federal, state, and employer health plans, should embrace value-based insurance design (VBID) for patients with diabetes.** In value-based insurance design, patients incur either no co-pays and deductibles, or very low ones, for medications to treat many chronic illnesses. These arrangements may also encourage them to take other steps to maintain their health, such as undergoing periodic tests or monitoring.

In recent years experiments with VBID have shown promising results in terms of producing better care for patients and higher medication adherence.<sup>63</sup> Early results from a diabetes-specific VBID plan offered through employers showed modest improvements among patients with diabetes in their adherence to metformin, anti-hypertensives, and statins

In 2017, CMS will launch a 7 state pilot program in which Medicare Advantage plans will experiment with models of value-based insurance design. Meanwhile, some major commercial health insurers, including Aetna and UnitedHealthCare, are experimenting with diabetes-specific benefit designs that take varying approaches to both prescription drug benefits and medical benefits. Reducing cost-related non-adherence, through VBID and similar arrangements, also should be a key goal for plans serving populations at special risk for diabetes and co-morbidities, including those enrolled in Medicaid or in the federally facilitated and state health exchanges created under the Affordable Care Act.

Plan sponsors and administrators of all of these arrangements should conduct rapid-cycle evaluations, adapting VBID plans for diabetes patients as lessons emerge. There is too much potential evident in the VBID experiments that have already occurred not to take advantage of the opportunity to refine and spread these models further.

## V. CONCLUSION

**T**he growth of diabetes poses a major challenge for the U.S. health care system, fiscal policy, and the economy as a whole. Although much can be accomplished in controlling and even preventing diabetes through more aggressive action to promote good nutrition and higher levels of physical activity, only better use of medications among patients suffering from diabetes and other associated conditions can ensure that we can meet shared Triple Aim goals: better health and satisfaction for each individual patient, better public health for all, at a cost that all can afford. Although many important steps have been taken in the 15 years to reform and transform our health care system, it is now time to take direct action to improve medication use in the care of diabetes, for the sake of patients and the broader public alike.

## *What does diabetes medication management look like in integrated systems?*

**D**iabetes care in some of the nation's most highly integrated health care systems provides a glimpse of what's possible under aggressive approaches to manage medication use. Patients treated at Kaiser Permanente and the Geisinger Health System may thus have an edge over the vast majority of diabetes patients, who are treated by community providers and rely on community-based pharmacies for their medication needs.

# Geisinger



## KAISER PERMANENTE®

Kaiser, which is both an insurer and a provider, is at risk for the care of all its patients. In 2005 Kaiser Permanente-Southern California created its Complete Care model, which has re-engineered care processes, including those that are medication related, to pro-actively meet the needs of patients with diabetes and other chronic illnesses. Geisinger carries the risk for many, although not all, of its patients, since many who are cared for by Geisinger's physicians and hospitals are also members of Geisinger's health plan or its Medicare Advantage plan. Geisinger's "All-or-None" Diabetes System of Care (DSC) model was adopted by Geisinger primary care practices in Pennsylvania in 2005.



The results to date suggest improved patient outcomes and lower costs. At Kaiser, the Complete Care model has resulted in substantial improvements in standard HEDIS measures among Medicare patients that have outpaced average improvement among providers nationwide. At Geisinger, use of the diabetes bundle by 178,000 patients lowered medical costs by 6.9 percent per member per month as compared to a control group of 159,000 patients, with higher cost savings for patients participating in the bundle over a prolonged period of time (14.7 percent lower for patients exposed five to six years. Patients involved in the bundle over three years also

demonstrated significant reduction in vascular damage as compared to usual care.

Key attributes of the Kaiser Permanente and Geisinger approaches to medication management are as follows:

- **Ability to assemble comprehensive data.** For example, in the Kaiser model, data on the medication adherence history of individual patients, including first-fill (primary medication non-adherence) alerts, are channeled through the electronic health record system from the Kaiser pharmacies directly to the care team. The data are used to spot gaps in adherence that should be addressed, either during in-person visits or through automated or live phone calls in between visits.
- **Processes to identify, document and resolve drug therapy problems.** Both models incorporate ‘touch points’ over time at which the patient’s medication regimen is reviewed. These steps allow identification of drug therapy problems such as drug-to-drug interactions, inappropriate dosing, dosing schedules that are difficult for patients to self-administer, and adherence problems. Drug therapy problems are flagged for resolution. Both models embed clinical pharmacists in most or all care teams to conduct medication therapy disease management.
- **Utilization of delegated authority.** Both models make extensive use of non-physician professionals, such as nurses and clinical pharmacists. In particular, both utilize collaborative practice agreements (CPAs) as allowed under state law, so that clinical pharmacists are not only capable of identifying drug therapy problems, but are also allowed to resolve specific drug therapy problems promptly under parameters set by the CPA.
- **Patient-centered assistance for self-management.** At Kaiser, care team members are trained to identify barriers to adherence among patients and offer solutions to patients. Geisinger generates patient “report cards” that are used as a teaching tool with patients.
- **Tracking process and outcomes measures.** Both systems link clinician payment to achieving specified overall targets in patient care. At Geisinger, for example, physician-led care teams are incentivized to improve patient outcomes simultaneously across core goals for patients with diabetes, including the ABC’s.

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