

# Taking Stock: Patient Medication Adherence and Chronic Disease Management

A NEHI White Paper



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# Executive Summary:

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This paper updates research that NEHI conducted a decade ago. There have been several important improvements in medication adherence fostered by changes in insurance coverage, the increased availability of generic, lower cost medications, provider incentives to address population health, and a host of innovations in technology and pharmaceutical care. Significant opportunities, however, remain to improve both medication adherence and the consistent, appropriate use of medications. Acknowledging that continued improvements require coordination and continuity of services that affect patient medication use, NEHI has made three recommendations involving the need for data and consistent measurement, the adoption of value based benefit design, and the addition of incentives for providers who have the ability to influence and support patients in managing chronic conditions.

**Poor adherence is a longstanding health risk:** Poor medication adherence creates significant health risks among patients with chronic illness. By some estimates up to 10 % of hospitalizations and 3 avoidable medical visits per patient per year can be attributed to non-adherence.<sup>1</sup>

**Poor adherence imposes significant costs on chronic disease management:** Poor medication adherence is a costly problem for chronic disease management. A recent systematic review of peer-reviewed adherence studies finds a median estimate of the cost burden of poor adherence to chronic disease medications is approximately \$17,000 per person, per year, (in 2015 dollars).<sup>1</sup>

Updated estimates of the overall burden of sub-optimal medication use exceed \$500 billion per year in the U.S., a burden caused by non-adherence and other closely related problems (such as prescription errors) that can result in non-adherence or sub-optimal adherence.<sup>1</sup>

**The burden of poor adherence and persistence grows over time:** When patients suffer interruptions in medication therapy or use their medications sub-optimally, chronic conditions worsen more rapidly than their natural progression. A 2013 analysis of medication adherence and persistence among Medicare patients with diabetes found gaps of up to \$500 per month in health care spending between persons who used blood pressure medications persistently, as compared to those who did not.<sup>2</sup>

**Multiple trends in policy and in the marketplace promise improvement in medication adherence:** Major developments include: the introduction of generic medications; access to prescription drug insurance coverage under Medicare Part D (2003), Affordable Care Act plans and state Medicaid expansions (2010); inclusion of adherence-related Star Ratings of Medicare and Medicare Advantage prescription drug plans; adherence goals within pharmacy pay-for-performance arrangements between pharmacies and health care payers; widespread adoption of electronic prescribing; and a wide range of innovations in technology and in pharmaceutical care, (automated reminder services, digital medication adherence apps, pharmacy services such as medication synchronization and pharmacist-led medication reviews).

**Statistical evidence on improvement in medication adherence is mixed:** Greater access to health insurance (such as the ACA expansions) increased utilization of prescription drugs, as measured by increased insurance claims. More recently, however, evidence from patient opinion surveys indicate that more patients are

discontinuing or rationing their prescription drugs as a result of higher drug costs and higher cost-sharing obligations under their insurance plans.

Yearly reports from the Medicare Star Ratings program suggest that adherence rates among Medicare patients have improved incrementally year to year for most patients on most Medicare drug plans. Publicly- available data on adherence rates among patients on non-Medicare insurance is, however, scant.

The impact of specific interventions aimed at adherence is unclear. Studies suggest that a wide variety of interventions can be effective, but most have shown a modest, incremental impact on raising adherence, at least when implemented on a stand-alone basis. Systematic reviews of evidence stress that achieving larger increases in adherence and persistence requires coordination and continuity of services that affect patient medication use, spanning low touch and high touch services, coupled with lower drug costs and insurance coverage that incentivizes adherence.

Consequently, we see three important avenues for improving medication adherence-related policy in the years ahead.

**1 Data:** Data on adherence continues to come mostly from one-time, point-in-time studies. There is no recurring, authoritative data source that allows patients, the public at large, and policymakers to discern trends in initiation and discontinuation of therapy, and gaps in continuous use of therapy (medication persistence). Longitudinal data is necessary to allow policymakers to compare adherence and persistence to trends in drug costs, to changes in insurance benefits that influence patient adherence (such as changes in cost sharing requirements), and access to medication management services. Longitudinal data to spot trends in medication persistence is necessary to adjust policy that will support continuous, optimal use of chronic disease medications. A technically qualified agency (such as the Government Accountability Office or the Congressional Budget Office) could devise a statistically valid and authoritative model to track adherence and persistence.

**2 Benefit Design and Management:** Carefully crafted, value-based insurance design (VBID), structured to lower patient out-of-pocket costs to encourage adherence and persistence have been successful without driving up overall spending.<sup>3</sup> Further progress with VBID will depend on finding actuarially sound ways to roll back the decade-long trend among employers and individual plan subscribers to choose high-deductible health plans. Medicare Advantage plans and other plans in which pharmacy benefit management is integrated with medical benefit management have been shown to support patient adherence, lowering avoidable health care use and reducing overall spending.<sup>4</sup> Integrated pharmacy-medical benefit management may be facilitated further by the recent absorption of major prescription benefit managers into large health insurers (i.e. Express Scripts into Cigna), or vice versa, (Aetna into CVS Health).

**3 Improving Incentives for Medication Management of the Chronically Ill:** Medication adherence improves when medication-related problems are identified and resolved. Pharmacist led medication care models (such as Medication Therapy Management -MTM- and the more expansive Comprehensive Medication Management -CMM- model) identify and resolve medication-related problems-- if pharmacists have requisite authority and payment support. MTM services are a Medicare Part D benefit but patient eligibility is limited, and coverage of similar services is limited among other health care payers.

Meanwhile, public and private payers have continued to move provider reimbursement towards value-based payments that reward physicians and health care delivery systems for improvements in population health among the chronically ill. Better alignment of incentives for delivery of pharmacy care such as MTM or CMM with the population health management incentives offered to providers through Accountable Care Organizations and similar payment models would improve the capability of patients, payers, and providers to improve chronic disease management.

## 1. Estimated Costs of Poor Adherence and Suboptimal Medication Use

Non-adherence, including failure to take medications as prescribed or taking them inconsistently, leads to avoidable illness and avoidable health care needs, such as physician or emergency department visits and hospitalizations. Most published estimates of the cost burden of non-adherence to chronic disease medications suggest that the burden is significant and on par with the cost burden associated with major areas of unmet medical need, such as addiction and mental illness. For example, a 2019 analysis of Medicare data estimated that the burden of non-adherence to common chronic disease medications in the Medicare Fee-for-Service program alone was approximately \$13 billion per year, including the cost of over 7 million avoidable inpatient hospital stays.<sup>5</sup>

Because of limitations in current methodologies and data sources, many studies that attempt to estimate the burden of poor medication adherence must estimate the overall cost of a larger set of medication-related problems, of which medication non-adherence *per se* is only one. Medication-related problems encountered by patients include problems such as misprescribed or poorly dosed medications, problems that result in sub-optimal therapy and may result in non-adherence or poor adherence incidentally. Nevertheless, the cost burden that can be reasonably associated with poor adherence is still significant.

A 2018 systematic review of medication adherence studies published in the British Medical Journal (BMJ) estimated costs of medication non-adherence in several categories of chronic disease, based on adjustments made in accordance with widely-accepted standards of cost effectiveness analysis.<sup>1</sup> Total patient costs associated with non-adherence among patients with cardiovascular disease were estimated at \$8,080 per year; among patients with diabetes at \$6,907 per year; and among patients with respiratory disease at \$6,689 per year. (All median adjusted estimates, in 2015 dollars, as calculated by the BMJ systematic review).

By way of comparison: total per capita U.S. health care spending for the same year (2015) totaled some \$9,990.<sup>6</sup>

The 2018 BMJ systematic review of adherence studies determined that the estimated median burden of medication non-adherence across all disease groups (an “all cause” estimate) totaled \$17,132 per-person, per-year (2015\$).<sup>1</sup> Other analysts have estimated an overall or aggregate annual cost burden on the U.S. health care system. In 2009, NEHI extrapolated previous estimates of medication treatment failures, including medication non-adherence and other medication-related problems, to find an estimated \$290 billion-per-year

burden on the U.S. health care system.<sup>7</sup> A 2013 analysis by Express Scripts, one of the largest U.S. prescription benefit managers, estimated the cost of non-adherence had reached \$337.1 billion, equivalent to \$394.27 billion in 2019.<sup>8</sup>

A detailed model released in 2018 by Watanabe & McInnis estimates that the overall burden of prescription drug-related morbidity and mortality is \$428.4 billion (2018\$).<sup>9</sup> This estimate is inclusive of multiple, inter-related types of medication treatment failure. Medication non-adherence can be a result of “upstream” problems such as a prescription prescribed in error, a prescription that causes unwanted side effects, an overall drug regimen that is overly confusing, or a regimen that includes drugs that can and should be safely discontinued. Patients may also be non-adherent to regimens of drugs that are safe and effective, but the patient is non-adherent for reasons of cost or because the patient is forgetful. In all these cases the patient’s history of prescription drug fills and refills might be reported as evidence of non-adherence, but interventions such as Medication Therapy Management (MTM) or Comprehensive Medication Management (CMM) might be required to address the more serious, underlying problems of uncoordinated or sub-optimal medication use and medication management.

Recent research that tracks health care use among patients who appear adherent and persistent in their long-term use of chronic disease medications associates persistent use with significant savings in health care spending that grow over time. For example, a 2013 analysis of adherence to anti-hypertensive medications among Medicare patients with diabetes indicated that monthly Medicare spending varied as much as \$300 between consistently high adhering and consistently low adhering patients, a gap that widened to \$500 per month over three years.<sup>2</sup> Medication use is thought to be a major factor in long-term reduction in treatment needs (or delays in the onset of) some of the most highly prevalent chronic conditions among U.S. patients, including hypertension, high cholesterol, type 2 diabetes, asthma and COPD.<sup>10</sup> The long-term reduction of heart disease and cardiovascular risks are attributed in part to the uptake of medications for control of high blood pressure and cholesterol, and recent research suggests that reduction in cardiovascular risks alone has been a major restraining factor in long-term health care spending in the U.S., yielding a (pre-COVID-19) level of per capita spending that is significantly below what would otherwise be expected.<sup>11</sup>

# Measuring Health vs. Measuring Patient Medication Adherence

Patients with chronic illness are not prescribed medications for the sake of taking medications. They are prescribed medications to reduce or delay the burden of chronic disease, and to do that they must take medications for as long as necessary: a lifetime for most patients.

The most accurate measurements of the clinical impact of medications are laboratory tests of patient blood plasma to observe levels of drugs in the body and to verify that drugs are metabolized as intended by a physician or other prescriber. Clinical trials for drug approvals require highly accurate data on how patients metabolize drugs over time, and in clinical trials the most highly accurate approach to measuring adherence entails statistical modeling of drug metabolism as confirmed by intermittent lab tests.<sup>12</sup> Continuous measurement of the patient's medication use enables observation of three essential elements of medication use: initiation of treatment, adherent execution, and persistent use for the entire duration of treatment.<sup>12</sup>

Innovations such as the “digital pill” may yet make continuous observation of patients' medication use and metabolism more practical.<sup>13</sup> For now, published measurements of patient medication adherence are data from patients' filling and re-filling prescriptions, an imperfect approach. In the words of leading adherence researchers, “the frequency of inadequate adherence is usually underestimated by pre-electronic methods [i.e. methods that do not model patient metabolism] and thus is clinically unrecognized as a frequent cause of failed treatment or underestimated effectiveness.”<sup>12</sup>

Studies of medication adherence generally track fill and refill data to delineate whether a patient picks up a medication once it is prescribed (*primary adherence*), and whether a patient fills and refills a prescription in keeping with the prescriber's instructions (*secondary adherence*.)<sup>14</sup> While these measurements are not as precise as laboratory tests and may underestimate the prevalence of poor adherence, they still point to significant levels of poor adherence among populations of chronically ill patients.

To be more specific: adherence data is often reported as the amount of time a patient appears to have medication on hand as evidenced by insurance claims; in the Medicare Part D prescription drug program patient adherence is reported as the percentage of Medicare patients who appear to have medications on hand 80% of time, (a “proportion of days covered” measurement). Two limitations of this type of measurement are an inability to capture whether a patient secured a medication for the first time (primary adherence), or whether the patient actually ingests a medication as prescribed, (an observation that could be made via a digital pill, or blood plasma lab tests.)<sup>15</sup>

## II. Measuring Adherence

### *Cost-Related Non-Adherence*

Cost is clearly a major cause of non-adherence. Findings on cost-related non-adherence is primarily reported by patients themselves in periodic surveys. Most surveys have not distinguished between primary medication adherence or secondary adherence (when a patient begins but discontinues therapy).

Self-reported rates of cost-related non-adherence among Medicare beneficiaries fell in the years following implementation of the Medicare Part D drug benefit and fell among non-Medicare patients after implementation of the Affordable Care Act. Reductions in non-adherence were observed among many at-risk populations, including uninsured adults, black Americans, individuals residing in the South and Midwest, persons with disabilities, and persons who reported their health as ‘fair’ or ‘poor’.<sup>16</sup>

Nevertheless surveys of low-income populations confirm that out-of-pocket costs are a major deterrent to adherence.<sup>17</sup> A 2015 study of 5,700 Medicare patients with AARP Medicare prescription drug coverage found that nearly 40% resorted to a cost-saving strategy (such as seeking free samples or splitting pills) to keep up with their medication treatment, likely resulting in under-reporting of patient medication adherence rates.<sup>18</sup>

Published surveys also suggest that cost-related non-adherence is not always caused by the affordability of a drug, but by other cost burdens faced by the patient. Patients may decide to fill or re-fill a prescription by balancing the cost of the medicine against their perception of how much benefit they receive from the medicine. Patients may also skip medications, including low-cost medications, that treat conditions that are asymptomatic, as hypertension and hyperlipidemia (high cholesterol) is for many patients.<sup>19</sup>

### *Primary Adherence and Non-Adherence*

Primary adherence occurs when a patient starts using a newly prescribed medication promptly, irrespective of the cause. Studies of primary non-adherence provide an important insight into how frequently patients initiate or re-initiate treatment. A 2010 study of over 75,000 American patients starting a new medication for chronic conditions found an overall non-adherence rate of 28%.<sup>20</sup> A meta-analysis of primary adherence studies conducted later in the decade (2018) suggests some improvement: primary non-adherence was estimated at approximately 21% for anti-cholesterol (statin) medications, 12.4% for hypertension medications, and 13.2% for oral diabetes medications.<sup>21</sup> Research findings tend to show that patients facing higher out-of-pocket costs are less likely to pick up a new medication.<sup>22</sup> However, most studies have not tracked patients over a longer period to determine how changes in drug prices and shifting health insurance requirements for patient cost-sharing influence primary medication non-adherence and the initiation of chronic disease therapy.<sup>22</sup>

### *Rates of Non-Adherence Measured Among Patients with Chronic Illness*

Multiple studies have estimated rates of adherence to chronic disease medications as observed in data from specific patient populations with specific insurance coverage (such as Medicare coverage), measured over a specific period. Few studies have observed adherence rates across a wide range of chronic diseases, measured in a consistent manner. Varying methodologies have been used to identify non-adherence even when applied to similar data sources, such as data from insurance claims, a point made in detail in a systematic review of



adherence studies published in BMJ in 2018.<sup>1</sup>

Data from Express Scripts, the large U.S. prescription benefit manager (PBM) provides comparable data from the middle of the past decade. The data suggests that improvements in adherence were minimal over that period.<sup>23</sup>

**TABLE 1 – Rates of Medication Non-Adherence by Condition**

Medication by Condition*	Non-Adherence in 2016	Non-Adherence in 2015	Non-Adherence in 2013
Asthma (Adult)	N/A**	45%	54%
Mental/Neurological	N/A**	42%	42%
Pulmonary Arterial Hypertension	N/A**	28%	25%
Asthma (Pediatric)	73%	78%	78%
Inflammatory conditions	42%	40%	41%
Diabetes	37%	39%	38%
Oncology (oral)	35%	38%	40%
Depression	34%	40%	40%
High Blood Pressure/ Heart Disease	28%	32%	29%
High Blood Cholesterol	26%	29%	28%
Multiple Sclerosis	24%	23%	29%
HIV	24%	23%	22%
Hepatitis C	8%	12%	N/A**

\*All data extracted from Express Scripts Drug Trend Reports from 2013, 2014 (published in 2015), and 2016. Percentages are rounded to the nearest whole number.

\*\* Data not reported for the given year.

Non-adherence rates generally decreased but remained high for both common conditions and for less prevalent diseases such as multiple sclerosis (23.9%). As might be expected, non-adherence rates were comparatively low for conditions generally treated with lower cost generic medications, such as anti-hypertension medications (27.8% in 2016) and cholesterol-lowering medications (26.4%). As of 2016, 72.5% of pediatric asthma patients were non-adherent, a decrease from 78.4% in 2013.

Both Express Scripts and a team led by a former chief medication officer of the American Diabetes Association Scripts estimate rates of non-adherence to diabetes medications to be 31%.<sup>24</sup>

# III. Moving the Needle? The Impact of Health Policy and Health Care Innovations on Medication Adherence

Over the last 15 years, health care reforms and technological innovations emerged to make medications and medication use more accessible, convenient and affordable, particularly for patients with chronic conditions. Recent studies shed some light on whether these changes have had an impact on longstanding gaps in patient medication adherence.

## *Expanded Insurance Coverage Has Increased Medication Use, But the Impact on Adherence Is Less Clear*

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The Medicare Part D prescription drug benefit, enacted in 2003 and fully implemented in 2006, increased use of prescription drugs among Medicare beneficiaries.<sup>25-28</sup> As noted above Medicare Part D and insurance expansions implemented through the Affordable Care Act reduced cost-related medication non-adherence among both Medicare and non-Medicare beneficiaries.<sup>16,29,30</sup> During initial implementation, Part D was shown to reduce but not entirely eliminate cost-related non-adherence.<sup>29</sup> After Part D was enacted in 2006, cost-related non-adherence fell from 5.4% in 2004 to 3.6% among older adults.<sup>16</sup> Similarly, cost-related non-adherence dropped among subsets of Americans younger than 65 years of age after the implementation of the Affordable Care Act and the 2014 Medicaid expansion in 27 states. These increases in insurance coverage have been associated with a nearly 2% decrease, from 9.1% in 2013 to 7.2% in 2015, in cost-related non-adherence among adults ages 26 to 64.

While expanded insurance coverage has clearly increased medication use, evidence that patients have achieved consistently good adherence rates due to expanded coverage is less conclusive.<sup>31</sup> Both employer-sponsored health insurance benefits and fully-insured, commercial health insurance have increased utilization of health plans that require cost-sharing by patients in the form of co-pays and deductibles. Over 50 percent of individuals with employer-sponsored health insurance are covered with high-deductible health plans, although use of high-deductible plans by employers may now be declining.<sup>32</sup> High-deductible plans have been shown to decrease the likelihood of consistent medication adherence.

The alternative approach is insurance benefit design that minimizes or eliminates patient cost-sharing for use of chronic disease medications. This approach is central to value-based insurance design (VBID), and research has indicated that carefully designed VBID plans can improve patient medication adherence to chronic disease medicines without an apparent increase in total health care spending.<sup>3,33</sup> Recent changes in federal policy push Medicare Advantage, the Affordable Care Act marketplace insurance plans and employer-sponsored health insurance plans in this direction. Internal Revenue Service guidance issued in 2019 now allows sponsors of high-deductible health plans to exempt insulin and a limited number of other essential chronic disease medications from the deductible patients must meet before their medication costs are covered by insurance.<sup>34</sup> CMS has also approved changes in the Senior Savings Model of Medicare Part D prescription drug coverage to lower patient out-of-pocket cost for insulin.<sup>35</sup> In May (2020) the Centers for Medicare and Medicaid Services (CMS) announced “broad support” for adoption of “VBID-X” benefit design in Affordable Care Act marketplace insurance plans. VBID-X plans aim to maintain the actuarial soundness of insurance plans by raising out-of-pocket-costs for certain services deemed to be of low value, while reducing or eliminating out-of-pocket costs

for services deemed to be of high-value, including essential chronic disease medications.<sup>36</sup>

### ***Incentives for Insurers and Pharmacy Pay-for-Performance Agreements Have Prompted Medication Adherence Improvements***

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Soon after implementation in 2006, the Medicare Part D program introduced medication adherence improvement goals for the private sector sponsors of Part D insurance and prescription drug coverage offered through Medicare Advantage plans. Private sector payers have followed suit by negotiating contract terms and financial incentives for health insurers, prescription benefit managers, and pharmacies requiring them to promote patient medication adherence.

Medicare's core adherence goals focus on essential chronic disease medications such as anti-hypertension, anti-cholesterol and oral diabetes medications. Medicare awards payment and other incentives through its Star Ratings program, in which insurers compete to demonstrate annual adherence improvements among its insured patients. The best performing plans demonstrate improvements in the proportion of patients that have medications available at least 80% of the time medication is required, (a standard defined as a PDC, or proportion-of-days-covered.)

Insurers primarily rely on pharmacies and pharmacists to offer the services that directly support or enable patients to achieve adherence. Contracts between pharmacies and insurers (or prescription benefit managers acting on behalf of insurers) specify adherence improvement goals and other quality improvement targets. These commitments are usually a condition for pharmacy participation in PBM networks, and financial incentives are offered to achieve performance goals. This pay-for-performance strategy largely originated with Medicare prescription drug plans looking to achieve the highest Star Ratings and the incentives The Centers for Medicare and Medicaid Services (CMS) offers to high-achieving plans, but the pay-for-performance movement is now extending to contracts between commercial health plans or Medicaid managed care plans and local pharmacies.

Reported rates of adherence within the Medicare Advantage plans improved by 2% each from 2018 to 2019 to 82% for oral diabetes medications, 84% for hypertension medications, and 80% for cholesterol medications. Similarly, average adherence in standalone Medicare Part D prescription drugs plan during this time increased by 1% for diabetes medications for an overall 83% adherence rate, and by 2% for hypertension and cholesterol medications to yield overall rates of 86% and 83% adherence, respectively.<sup>37</sup> Recent research also suggests that Star Rating incentives for adherence not only improved adherence for the three types of medication on which ratings are determined but have also improved adherence for other medications used by Medicare patients.<sup>38</sup>

### ***Innovations in Pharmacist Practice and Pharmacy Operations***

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As evidence accumulates on the effectiveness of financial and contract incentives to payers and pharmacies on medication adherence, a separate body of evidence is accumulating on the impact of specific innovations in pharmacist practice and pharmacy operations. There is a wide and growing array of interventions, services and tools that pharmacists and pharmacies can apply to raising patient medication adherence rates when supported by adequate payment and incentives. They range from passive supports such as pillboxes and adherence-friendly drug packaging, to automated tools such as telephone or text-messaged refill

reminders, to more hands-on services such as medication synchronization and medication reviews. Hands-on interventions that are heavily directed towards patients with chronic illness and complex medication regimens include Medication Therapy Management (MTM) and Comprehensive Medication Management (CMM).

## *Medication Therapy Management (MTM) and Comprehensive Medication Management (CMM)*

The 2003 federal legislation that created the Medicare Part D prescription drug insurance program includes a Medication Therapy Management (MTM) benefit that is available to Medicare beneficiaries who meet eligibility qualifications based on their health risks and medication needs. Pharmacists are compensated for providing MTM services to eligible Medicare patients. CMS sets broad goals for the MTM benefit. Medicare Part D insurers must offer plans that aim to optimize use of Part D medications, including improvements in adherence, reduce adverse events and other medication safety risks. Part D insurers have discretion in the design of MTM services and in patients they choose to target, although in practice Part D plans focus MTM services heavily on patients with multiple chronic conditions.<sup>39</sup>

The services provided under MTM are wide-ranging, but many focus on behaviors, activities and tasks that promote improved medication adherence in patient populations. These services can include reviewing medication therapies, formulating a medication treatment plan, documenting care delivered, communicating findings to primary care providers, and providing verbal education and training to enhance patient understanding of their prescriptions and how to appropriately use medication.<sup>40</sup> Studies have found that MTM can reduce adverse patient outcomes that result from poor medication adherence, such as hospital readmissions, and patients were satisfied receiving MTM counseling from pharmacists.<sup>41,42</sup> In addition, targeted medication review and comprehensive medication review, two MTM services, can increase adherence and reduce acute inpatient admissions and emergency department visits.<sup>43</sup>

As actually practiced the services provided through the Medicare MTM benefit are constrained by the funds available to pay pharmacists from the budgets Part D plans submit to CMS for approval every year. Pharmacists also cite the operational difficulties of fitting MTM services into daily pharmacy workflows. More recently, pharmacists and pharmacies assert that MTM fees are offset by fees “clawed back” from pharmacies by pharmacy benefit managers to make final adjustments between PBMs and pharmacies for the cost of drugs purchased by pharmacies and billed to PBMs and insurers, (see section on direct and indirect remuneration, DIR, below).

Medicare MTM services also fall short of a more expansive, evidence-based and pharmacist-led care protocol known as Comprehensive Medication Management (CMM). The CMM care protocol requires pharmacists or other providers to identify a defined set of drug therapy problems (DTPs) in a patient’s medication regimen, devise a plan of action to correct the DTPs and, either take action directly to correct the DTPS or follow up with prescribers who are authorized to correct the DTPs. DTPs are ordinarily defined to include poor medication adherence and other problems that pose a safety risk to the patient. Other categories include drug safety problems, drug efficacy problems (such as drugs prescribed at dosage levels that are under- or over-dosed to meet the patient’s needs), “cost efficacy” problems (such as prescribing expensive drugs when cheaper

alternatives are appropriate), and unnecessary therapies (such as drugs that can be discontinued). While poor adherence is only one among the several categories of DTPs, nearly all DTPs delay, disrupt, or reduce appropriate medication adherence and persistence if they are not corrected.

Because of its focus on defining and resolving a wide range of drug therapy problems, wider adoption of the CMM could be an opportunity for averting an equally wide range of preventable medical costs. A recent analysis estimated the potential yearly impact at \$528 billion per year in savings to the U.S. health care system.<sup>9</sup> Clinical pharmacists embedded in primary care teams are uniquely positioned to provide CMM as a member of a coordinated care team, and pilot projects with embedded pharmacists have shown promising results, including increased patient and provider satisfaction, improved therapeutic goal attainment, and reduced drug spending, hospital readmissions, and emergency department visits.<sup>44-46</sup> In one CMM program, two pharmacists were able to identify more than 9,000 medication therapy problems and perform over 14,000 interventions for 3,777 unique patients over just four years.<sup>47</sup> In addition, physicians have found integration of pharmacists to provide CMM furthers clinical outcomes and improves access to drug knowledge.<sup>48</sup> Pilot projects demonstrating CMM implementation with Medicaid patients and patients at high-risk have demonstrated an ability to identify and rectify specific drug therapy problems, leading to a positive return on investment.<sup>49</sup> Last but not least, pharmacist inclusion in CMM programs has the potential to ameliorate current shortages in the primary care workforce and allows physicians to be more efficient and effective in their work.<sup>49</sup>

Despite the success of some pilot CMM projects, the CMM model has not been adopted at scale in the U.S. health care system. When fully implemented the CMM model allows pharmacists to access patients' clinical information (such as data from electronic health records) and allows pharmacists to practice at a "top of the license" fashion by authorizing them to resolve drug therapy problems on their own initiative. Pharmacists in most of the states can gain this authority through formal agreements with physicians under collaborative practice agreements. Otherwise the scope-of-practice enjoyed by pharmacists is regulated at the state level in state law and regulation. While most states have expanded pharmacist scope-of-practice over the past 30 years (to authorize flu immunizations at pharmacies, for example), no state allows pharmacists the full range of authority on prescribing, describing and readjusting patient medications that is required by the CMM model.

## Other Pharmacist and Pharmacy-led Interventions

Research has shown that pharmacists, both in the clinic environment and in the community, can positively impact medication adherence. Pharmacists are easily accessible and have regular contact with patients who require chronic disease medications, allowing them to build rapport.<sup>50</sup> While each of the following strategies show promise, combinations of these strategies may prove more successful.

- ***Medication synchronization***

Medication synchronization services allow patients to retrieve all of their prescription medications in one visit to the pharmacy, rather than individual visits when prescriptions run out.<sup>51</sup> Offered in approximately 11% of retail pharmacies,<sup>51</sup> medication synchronization programs often include monthly appointments with pharmacists, and have led to modest increases in prescription days covered.<sup>52,53</sup> Providing flexibility and patient autonomy in choice of refill timing date helps improve adoption.<sup>51</sup>

- ***Adherence packaging***

Calendared blister packaging, also called bubble packaging, has been associated with increased medication adherence, improvement in patient satisfaction, and easier adherence monitoring.<sup>54</sup>

- ***Reminder devices and technologies (i.e. pill boxes, smart pill bottles)***

Smart pill bottles and other medication adherence technologies, which may come with blinking lights or chimes, have been found to increase adherence.<sup>55</sup> These devices have shown significant associations between patient-reported adherence and actual adherence.<sup>56</sup> Patients have found these technologies easy to use.<sup>56</sup>

- ***Medication reviews***

Medication reviews combined with education and counseling by pharmacists have been used to improve medication adherence, as well.<sup>57</sup> This approach requires close coordination between the pharmacist and the clinical team, as well as provision of adequate resources for the pharmacist to access sufficient clinical information.

- ***Medication reconciliation***

Effective medication reconciliation, in which a pharmacist compares current and proposed medication regimens, helps decrease errors and omissions in medication prescription and compliance. Reconciliation is especially important during transitions of care,<sup>58</sup> and have been associated with decreased hospital readmissions and fewer adverse drug events.<sup>59</sup>

- ***Motivational interviewing by pharmacists***

Motivational interviewing by pharmacists has been shown to improve medication adherence in chronic disease management. While motivational interviewing can be completed over the phone and face-to-face, in-person interactions were found to have a more positive effect.<sup>60</sup>

- *Medication reminders and automated messaging (text messaging, robocalls)*

Refill reminders communicated to patients by postcard, phone calls and text messages have found mixed results, but may be more effective when combined with patient education or other strategies.<sup>61</sup> Automated messaging, whether by phone calls, text messages, or emails to clinicians have been used to increase adherence.<sup>61</sup> However, more advanced technologies may improve the pharmacist-patient relationship further and lead to better monitoring and adherence.<sup>62</sup>

## *Predictive Analytics Targeting Patients Needing Medication Management and Adherence Support*

Some insurers and PBMs support pharmacist services through sharing data and analytics that identify patients at risk for poor adherence and sub-optimal medication use. Data collection and analysis has been greatly facilitated by rapid uptake of electronic prescribing over the last decade. Data derived from electronic prescribing not only enables rapid calculation of adherence rates, but predictive analysis enables payers or providers to identify patients at risk for non-adherence, and to tailor interventions (such as patient counseling) to patients who have discontinued medication use or at risk for discontinuing it.<sup>63</sup> While approximately 85% of prescriptions are now sent electronically, only 84% of electronically-prescribed medications are dispensed, suggesting that at least 16% of e-prescriptions can be analyzed for appropriate follow-up.<sup>64</sup> In addition, 73% of prescribers use e-prescription services, demonstrating that data derived from these systems is still not capturing prescriptions from 27% of prescribers.<sup>63</sup>

# Recommendations

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Peer-reviewed systematic reviews of medication adherence studies continue to indicate that poor medication adherence remains a significant problem that leads to avoidable illness and injury among patients with chronic disease, and to preventable health care costs that grow over time as gaps in medication persistence lead to avoidable progression of disease.

Expansions in insurance coverage and innovations in technology and pharmacy practice have shown promising results in creating greater access to prescription drugs and raising rates of medication adherence, but most results are modest. Meanwhile, published data on trends in medication adherence and persistence remain remarkably limited. Data held by health care payers and providers in the private sector may well be more rich than data available to the public and to public policymakers, but gaps in publicly available data make it more difficult for all stakeholders to find consensus on stronger action to close gaps in adherence and persistence.

We see three over-arching areas for action.

## 1 | Data:

In 2012 the Congressional Budget Office recognized medication adherence as a factor in reducing Medicare costs when it revised its fiscal scoring methodology to recognize a 0.2% decrease in Medicare spending for each 1% increase in prescriptions filled by Medicare patients. A new methodology to track specific trends in patient medication adherence and persistence is a logical next step, particularly at a point when Congress and the Administration are actively debating new policy to make prescription costs more affordable to patients, presumably to make patients' access and adherence to therapy easier.

The Congressional Budget Office or another technically qualified agency (such as the Government Accountability Office or the CMS Actuary) should devise a statistically valid and authoritative model to identify trends in patient medication adherence on a recurring basis. Priority should be placed on models to track adherence and persistence to the medications commonly used by patients with highly prevalent chronic diseases, such as type 2 diabetes, and highly prevalent co-morbidities such as heart disease. Longitudinal data on adherence and persistence will be essential in discerning trends in initiation and discontinuation of therapy as well as gaps in persistence. Without understanding these trends, it will be exceedingly difficult to identify the policies and services that are effective in supporting adherence and persistence. An especially high priority should be placed on tracking longitudinal data on the relationship between patient out-of-pocket cost spending and medication adherence and persistence, as this is essential to ensuring that insurance benefit design is both supportive of adherence and is actuarially sound as well.



## 2 | Benefit Design and Management:

As out-of-pocket cost obligations such as co-pays and deductibles have increased in recent years, patients have increasingly reported greater difficulty in starting prescription drug therapy and maintaining adherence. Value-based insurance design (VBID) reduces out-of-pocket cost obligations on high-value drugs such as drugs commonly used in chronic disease management, while sometimes increasing patient costs for use of drugs with less evidence of effectiveness. After a period of experimentation, the Medicare program now allows Medicare prescription drug plans to offer VBID-based drug coverage in all 50 states and, as noted above, CMS has expressed broad support for greater adoption of VBID in Affordable Care Act marketplace plans. More recently many employers and commercial health plans throughout the country have voluntarily lowered patient cost-sharing for insulin. While this is not been characterized as a “VBID-for-insulin” trend, the effect is the same: costs are lowered for highly valuable and often life-saving drugs for patients who are otherwise at risk for costly medical complications. CMS and other federal policymakers should encourage further experimentation (for example, through CMS Innovation Center projects) to discover actuarially sound strategies for lowering out of pocket costs for highly valuable chronic disease medications while maintaining the overall affordability of health insurance premiums. Ongoing research is also needed to track whether employers and other sponsors of high-deductible health plans are taking advantage of the 2019 IRS guidance (IRS Notice 2019-45) that allows plan sponsors to exempt chronic disease medications from the deductibles that patients must satisfy if they are covered by a high-deductible health insurance plan.

## 3 | Improving Incentives for Medication Management of the Chronically Ill:

Poor medication adherence and persistence has multiple root causes. Rectifying poor adherence and persistence among patients at the highest risk for disease progression and complications, and thus for avoidable health care spending, depends on identifying these root causes. Medication Therapy Management (MTM) and the more expansive model of Comprehensive Medication Management (CMM) have shown promise, but in practice their impact is blunted by multiple factors that include restrictions on the scope of practice for pharmacists that vary from state to state. Limited reimbursement is a further issue.

MTM and CMM are underutilized despite significant evidence that CMM improves patient clinical outcomes and decreases costs.<sup>65,66</sup> Insufficient time to provide comprehensive education and counseling to patients coupled with limited reimbursement hinders successful uptake of MTM and CMM among pharmacists. Solutions aimed at improving uptake of MTM and CMM include embedding pharmacists in integrated care programs like accountable care organizations, patient centered medical homes, and federally qualified health centers, and allowing pharmacists to bill Medicare directly for CMM services by designating pharmacists as Medicare providers.

Embedding pharmacists into integrated care programs helps to provide open lines of communication among providers and necessary access to medical records for pharmacists. Education and counseling by pharmacists can happen remotely via telehealth,<sup>67</sup> or by referral for immediate or appointment-based on site counseling.<sup>68</sup> Collaborative drug therapy agreements, incident-to billing and shared savings agreements in accountable care organizations, can facilitate and improve reimbursement for MTM and CMM services.<sup>65</sup>

While integrated care programs provide a feasible setting for MTM and CMM, patients residing in rural areas may have limited access to comprehensive programs and rely more heavily on community pharmacists.<sup>69</sup> Community pharmacists can still be integrated with primary care practices through collaborative practice agreements that create a virtual care team that spans physicians and their staffs working in the clinic and pharmacists working in local drug stores.<sup>70</sup> One leading example of innovation in virtual care teams is the community pharmacy enhanced services model pioneered by Community Care of North Carolina, and supported through the CMS Innovation Center (CMMI). Studies to date have shown that enhanced services (such as timely medication reconciliations and medication synchronization), led by community pharmacists and targeted at patients identified with the most complex medication management needs or at the highest risk for medical complications, can be administered cost-effectively and achieve measurable gains in patient medication adherence. The enhanced pharmacy services model has now been deployed to community pharmacies in over 30 states.<sup>71</sup> The community pharmacy enhanced services model reimburses pharmacists according to the intensity of services they deliver to each targeted patient.<sup>72</sup> This kind of integrated and well targeted set of services should be promoted more widely through the health care system in order to make measurable improvements in medication use, patient adherence and persistence.

Community pharmacists have identified direct and indirect reimbursement fees (DIR) as a barrier to expanding community-based pharmacy services among Medicare patients. DIR fees are assessed on pharmacies retroactively as part of an overall financial reconciliation in which Medicare prescription drug plans pass rebates back to the Medicare program, but in recent years other, unrelated fees have been assessed by health plans and prescription benefit managers as well. The U.S. Senate Finance Committee has called on the Department of Health and Human Services to clarify and reform allowable DIR fees, citing the impact of DIR fees on patient medication adherence among patients reliant on pharmacies that have reduced or closed operations entirely due to DIR obligations.<sup>73</sup> Resolution of the DIR controversy will be an important step in clarifying the future profitability of community pharmacies, their ability to deliver medication management services, and hence the need for improvements in reimbursement available to pharmacists.

Finally, value-based payment arrangements between pharmaceutical manufacturers and health care payers represent another approach to targeted improvements in patient medication adherence and persistence. Under value-based arrangements manufacturers and payers agree to make the final cost of purchasing a drug contingent on achieving pre-defined outcomes among the patients using a drug. Under numerous value-based agreements improvements in medication adherence is a pre-defined goal. Most value-based agreements are confidential, and evaluation of results has been limited as a result. Nonetheless, industry surveys generally find that U.S. payers and drug manufacturers see these arrangements as a payment strategy that could be used more widely to improve medication therapy among patients.<sup>74</sup> Greater use of value-based arrangements, including arrangements offering greater benefits to patients, is constrained by a series of regulatory barriers.<sup>75</sup> Reasonable accommodations within key regulatory programs and their enforcement (the Medicaid Drug Rebate Program and Anti-Kickback Statute enforcement) should be considered as a step towards support for improved patient medication adherence and persistence throughout the health care system.<sup>76</sup>

# Conclusion

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Over 60 percent of Americans have one chronic condition, and over 40 percent have two or more. Nearly half of all Americans use at least one medication every day, and about 25 percent use at least three every day. Medications are discussed in three out of every four patient visits with a physician. Chronic disease remains a major driver of illness, premature death, and health care spending cost in the United States, and good use of medications remains imperative for relieving this burden on public health and the economy.<sup>74</sup>

As noted in this paper, many trends in public policy and in the health care marketplace have emerged over the last 20 years to improve access to medications and support adherence. For all that, measurement of improvements in adherence and medication persistence remains imprecise. Better data would give a more consistent picture of where policy and practice need to be improved. In the meantime, many promising innovations in insurance design, pharmacy practice, and in technology show promise in improving medication use, adherence and persistence in chronically ill patients. A major priority for all stakeholders – patients, payers, providers, pharmacies and drug manufacturers – is innovation that integrates the best of these developments into more consistent and comprehensive support for the millions of American patients who use chronic disease medications.



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## About NEHI

NEHI is a national nonprofit, nonpartisan organization composed of stakeholders from across all key sectors of health and health care. Its mission is to advance innovations that improve health, enhance the quality of health care, and achieve greater value for the money spent.

NEHI brings together expert stakeholder perspectives with relevant research to devise policies that speed the adoption of innovations.

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