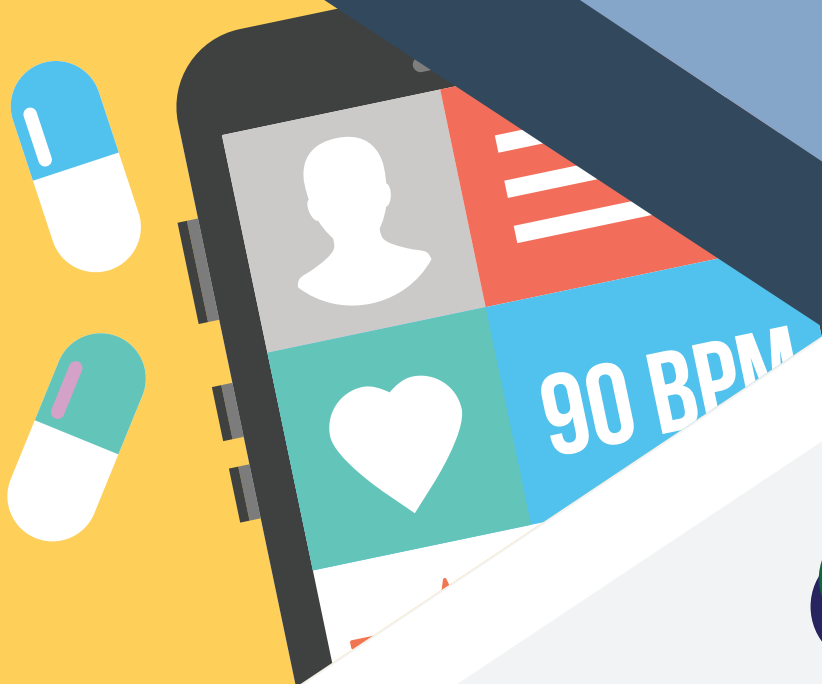


A TREATABLE PROBLEM:

ADDRESSING MEDICATION
NONADHERENCE BY REFORMING
GOVERNMENT BARRIERS TO
CARE COORDINATION
EMBARGOED



Prescriptions for a
Healthy America

"A Partnership for Advancing Medication Adherence"

WHITE PAPER . OCTOBER 2017

EXECUTIVE SUMMARY

Nonadherence has an impact on health care spending roughly comparable to that of smoking¹, and yet receives only a fraction of the attention. The direct medical costs and consequences associated with not taking medications as prescribed is estimated to range from 7 percent to 13 percent of national health spending annually—"roughly 250 billion to 460 billion in 2017, translating to a potential cost to consumers and taxpayers of \$6 trillion over the next ten years alone."²

A concerted effort to encourage better use of medicines, say, on the scale of anti-smoking campaigns, would benefit not only the chronically ill, who are at risk of disease progression and physical decline, but also healthy consumers, whose insurance premiums and taxes pay most of the bills. For example, 37 percent of Medicare spending goes toward the treatment of patients with heart failure, but just 40 percent of patients with congestive heart failure are adherent to their prescription regimens.³

The state of the art in medication adherence is still evolving, and more experimentation and collaboration is needed to determine what solutions work best. A range of stakeholders are interested in providing adherence services to ensure appropriate use of medicines. These efforts are made more difficult by the lack of clear guidance under the Federal Anti-Kickback Statute (AKS), which has limited stakeholders' comfort with supporting adherence for patients with insurance through Federal

healthcare programs such as Medicare and Medicaid.

The AKS is a broadly worded statute that prohibits providing anything of value to induce the purchase of items or services reimbursed by Federal health care programs. Due to the broad reach of the law, Congress empowered the Office of the Inspector General of the Department of Health and Human Services (OIG) to create "safe harbors" to protect certain beneficial arrangements, where the risk of fraud and abuse is minimal. In fact, 28 "safe harbors" for a range of activities exist today. Creating a narrowly tailored safe harbor for adherence programs would provide clarity to stakeholders who are seeking to implement programs that can improve outcomes for patients and lead to reductions in medical spending.

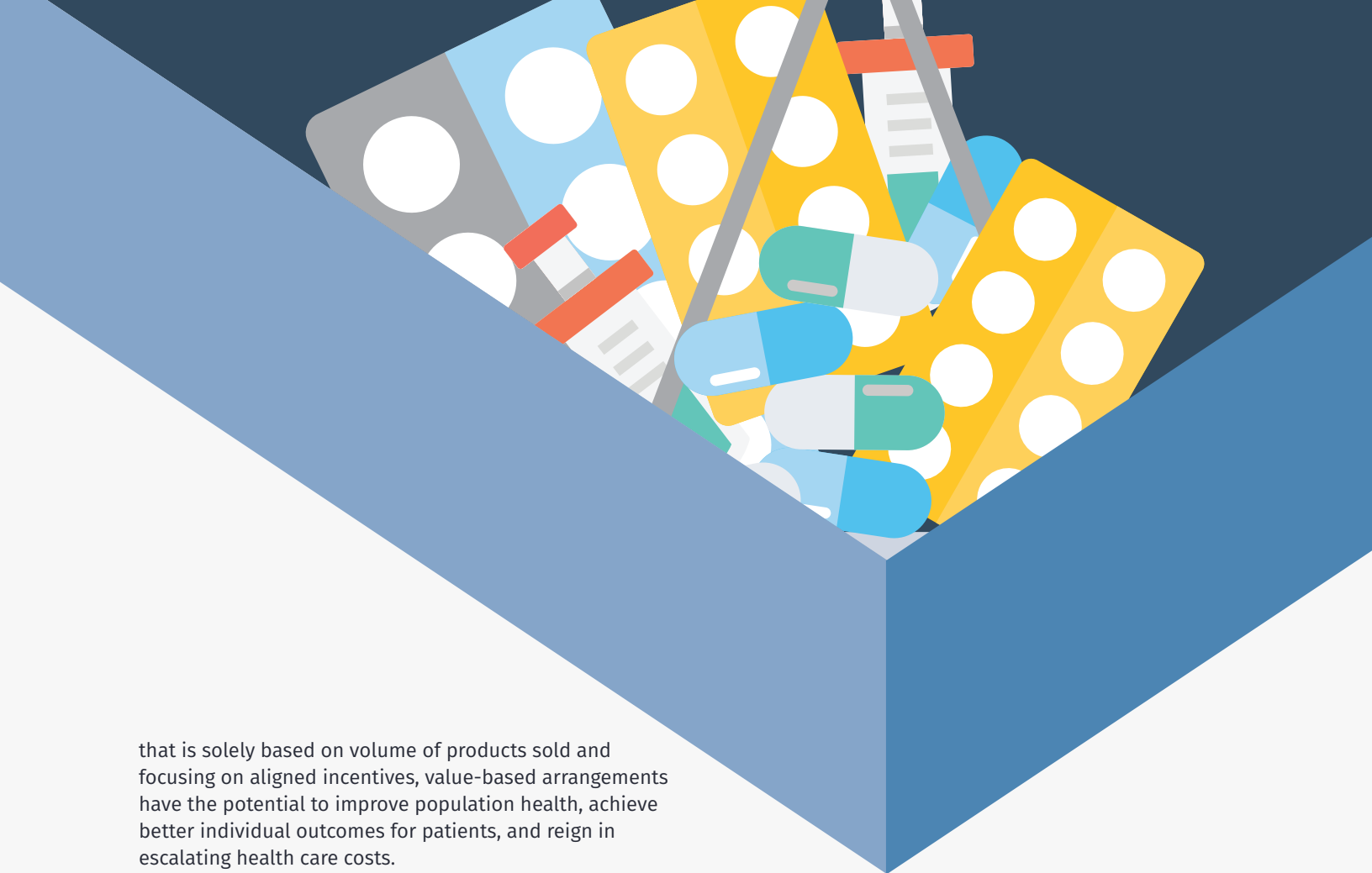
In addition benefiting to patient health generally, medication adherence monitoring and support can facilitate certain value-based arrangements between pharmaceutical manufacturers and payers. Payers and manufacturers are exploring innovative pricing and contracting models that tie payment more closely to patient outcomes, which can encompass an assortment of strategies not seen in the more conventional volume-based purchasing agreements. Although the components of these innovative contracts can vary, they typically include payment that is tied to achievement of specific goals, performance benchmarks, or improvement in patient outcomes. By moving away from reimbursement

¹ Victor U Ekpui and Abraham K Brown, "The Economic Impact of Smoking and of Reducing Smoking Prevalence: Review of Evidence", US National Library of Medicine, National Institutes of Health, July 14, 2015. accessed online on 6/29/16. Estimates of the proportion of health care expenditure attributable to smoking range between 6 percent and 18 percent across different states.

² The commonly cited low-end estimate of \$100 billion a year is based on costs in 2000. In the interim, national health expenditures (NHE) have increased 257 percent. (See, for example: Lars Osterberg and Terrence Blaschke, "Adherence to Medication", New England Journal of Medicine. August 4, 2005.) The commonly cited high-end estimate of \$289 billion a year is based on a study of costs in 2000, updated to 2008. Since 2008, NHE has increased 47 percent. (See: "Thinking Outside the Pillbox," New England Healthcare Institute. August 2009.) The Centers for Medicare and Medicaid Services estimates that NHE will total \$44 trillion during 2016-2025, a 9 year period. Over ten years, NHE would total about \$50 trillion, of which 13 percent is equal to \$6.5 trillion.

³ Roebuck C, Liberman J, et al., "Medication Adherence Leads to Lower Health Care Use and Costs Despite Increased Drug Spending", Health Affairs. January 2011





that is solely based on volume of products sold and focusing on aligned incentives, value-based arrangements have the potential to improve population health, achieve better individual outcomes for patients, and reign in escalating health care costs.

Manufacturers exploring these contracts may be interested in ensuring that prescribed medicines are being used appropriately, so that measured outcomes in value-based arrangements are based on proper adherence, and to ensure that any poor outcomes do not result from not taking medications improperly.

However, manufacturers' willingness to support appropriate use of medicines may be limited by the lack of clear guidance regarding adherence support services under the AKS. By addressing these concerns, an adherence safe harbor would allow for more of these beneficial agreements while also encouraging more appropriate use of medicines.

Other players in the care continuum—particularly, hospitals and physicians, but also the government itself—lack incentives and capacity to carry out adherence and medication management programs on the scale that numerous peer-reviewed studies indicate would be

beneficial. Efforts must be made to strengthen and reorient incentives to encourage collaboration in this area.

In this paper, we review the evidence on various adherence programs within and outside of federal health programs and argue that vigorous innovation requires more regulatory certainty than currently exists. More value-based agreements would result, generating lower costs to patients and taxpayers, while improving population health. We conclude by outlining a proposal for an explicit medication adherence safe harbor under the AKS. In short, outdated government rules should be modernized to allow private sector collaboration where it results in savings and care improvement.



Prescriptions for a
Healthy America

"A Partnership for Advancing Medication Adherence"

ADHERENCE CAN IMPROVE OUTCOMES AND REDUCE HEALTH SYSTEM COSTS

Medication adherence occurs when patients take their medications as prescribed—i.e., according to the specific dosage, time, and frequency prescribed. A breakdown in any one of these elements may result in unanticipated side effects and complications. Despite this, studies have shown consistently that 50 percent of medications for chronic disease are not taken as prescribed and 20 to 30 percent of medication prescriptions are never filled.⁴

Nonadherence negatively affects patient health by reducing the ability of health care providers to manage and control diseases effectively. Nonadherence causes an estimated 125,000 deaths a year and up to 10 percent of all hospitalizations.⁵ Nonadherent patients are more likely to experience preventable disease progression, increased hospitalizations, doctor and emergency room visits and other problems arising from poor health. Medication adherence is particularly important in supporting positive clinical outcomes for a broad range of serious chronic conditions, including HIV/AIDS,⁶ heart disease,⁷ respiratory disease,⁸ diabetes,⁹ and depression.¹⁰ Nonadherence may allow many chronic conditions to progress, leading to costly, avoidable complications and reduced well-being. Addressing this problem becomes more pressing as the number of Americans with chronic illnesses increases.¹¹

Among the Medicare population, where two-thirds of all beneficiaries have multiple chronic conditions, adherence rates are especially alarming.¹² Primary nonadherence—the failure to fill a new prescription—is a significant problem for many, including 45 percent of Medicare beneficiaries with diabetes. A shocking

⁴ Viswanathan M, Golin CE, Jones CD, et al. Medication Adherence Interventions: Comparative Effectiveness. Closing the Quality Gap: Revisiting the State of the Science. September 2012. ⁵ Viswanathan, M., et al. Interventions to Improve Adherence to Self-administered Medications for Chronic Diseases in the United States: A Systematic Review, ANN INTERN MED. 2012;157(11):785-795.

⁶ CC Carpenter, DA Cooper, MA Fischl, JM Gatell, BG Gazzard, SM Hammer, et al. Antiretroviral therapy in adults: updated recommendations of the International AIDS Society - USA Panel. JAMA 2000;283:381-390; Durant J, Clevenbergh P, Halfon P, Deljudice P, Porsin S, Simonet P, et al. Drug-Resistance Genotyping in HIV-1 Therapy: the VIRADAPT Randomised Controlled Trial. LANCET 1999;353:2195-2199.

⁷ N. K. Choudhry, Untangling the Relationship Between Medication Adherence and Post-Myocardial Infarction Outcomes, AM. HEART J. 2014; 167(1):51-58 (finding that achieving adherence of 80 percent or higher to their prescription medications reduced the risk of hospital readmission after a heart attack); D.G. Pittman et al. Adherence to Statins, Subsequent Healthcare Costs, and Cardiovascular Hospitalizations. AM. J. OF CARDIOLOGY (June 2011) (finding that patients with high rates of adherence to statins had significantly lower total healthcare costs and lower risk of cardiovascular disease-related hospitalizations, relative to nonadherent patients).

⁸ Albrecht JS, Khokhar B, et al. Adherence and healthcare utilization among older adults with COPD and depression. Respir Med. 2017. 129:53-58

⁹ Khunti K, et al. Association Between Adherence to Pharmacotherapy and Outcomes in Type 2 Diabetes: A Meta-analysis. Diabetes Care. 2017 (early online)





THE BENEFITS ATTRIBUTED TO IMPROVED SELF-MANAGEMENT OF CHRONIC DISEASES TO EXCEED COST OF ADHERENCE PROGRAMS BY

10:1



MOST SAVINGS FROM FEWER DOCTOR VISITS, EMERGENCY ROOM VISITS, HOSPITAL ADMISSIONS, AND ADDITIONAL MEDICATIONS.¹⁶

60 percent of patients with chronic obstructive pulmonary disease (COPD) are nonadherent.¹³ Even among beneficiaries who did fill a prescription, adherence was poor, with just 25 percent of beneficiaries still taking their medicine after three years.¹⁴

Proper medication adherence is associated with a reduction in overall healthcare spending.¹⁵ Studies have found the benefits attributable to improved self-management of chronic diseases to exceed the cost of adherence programs by a ratio of 10:1—with most savings coming from fewer doctor visits, emergency room visits, hospital admissions, and additional medications.¹⁶

¹⁰ Catherine A. Melfi, et al. The Effect of Adherence to Antidepressant Treatment Guidelines on Relapse and Recurrence of Depression, ARCH GEN PSYCHIATRY 1998;55(12):1128-1132 (concluding that adherence to depression treatment guidelines reduces the probability of relapse or recurrence).

¹¹ Chronic diseases affect approximately 133 million Americans, representing over 40% of the population. Centers for Disease Control and Prevention. The Power of Prevention. (2009) By 2020, the number of Americans with chronic diseases is projected to increase to approximately 157 million. Tackling the burden of chronic diseases in the USA. Lancet 2009;373 (9659):185.

¹² Centers for Medicare and Medicaid Services. Chronic Conditions among Medicare Beneficiaries, Chartbook, 2012 Edition.

¹³ Stuart B., Loh, J. E. Xu, Roberto P., Dougherty S., Chartbook: Medication Utilization Patterns and Outcomes among Medicare Part D Enrollees with Common Chronic Conditions, 2014.

¹⁴ Id.

¹⁵ Roebuck MC, et al. Medication Adherence Leads to Lower Health Care Use and Costs Despite Increased Drug Spending. 2011. Health Affairs, 30 (1): 91-99.

¹⁶ Viswanathan M, supra, at 10.

MEDICATION ADHERENCE HAS BEEN RECOGNIZED AS A PRIORITY BY POLICYMAKERS

Congress first recognized the importance of medication adherence in the 2003 Medicare Modernization Act (MMA), which created the Medicare Part D program (the outpatient prescription drug benefit). The MMA requires Part D plans to furnish Medication Therapy Management (MTM) services to improve prescription drug use and outcomes among targeted high-risk beneficiaries with multiple chronic conditions, who are taking multiple medications meeting a minimum cost threshold (\$3,919 in 2017). As part of this MTM requirement, the MMA included a provision encouraging MTM services that “[increase] enrollee adherence with prescription medication regimens through medication refill reminders, special packaging, and other compliance programs and other appropriate means...”¹⁷

The Congressional Budget Office (CBO) has recognized the unique role that pharmaceuticals play in lowering overall health costs. In November 2012, the CBO adjusted its scoring methodology to account for savings in other healthcare services that accompany an increase in the use of prescription medicines in the Medicare population.¹⁸

A goal of the 2010 Affordable Care Act (ACA), beyond

expanding health insurance coverage, was to shift the focus of the healthcare delivery and payment system from paying for discrete services provided (volume) toward reimbursements tied to better quality, enhanced efficiency, and lower costs (value). Because value-based models change incentives related to and the culture around care delivery, their benefits arguably extend beyond Federal Health Care Programs, to the private sector.¹⁹ The ACA strengthened the 2003 MTM law by requiring MTM services be targeted to beneficiaries “that include, at a minimum, the following to increase adherence to prescription medications . . . (i) An annual comprehensive medication review [and]... (ii) Follow-up interventions as warranted...”²⁰

The Centers for Medicare and Medicaid Services (CMS) have also included three medication adherence measures, pictured below, in its Part D Star Rating system, which provides an easy to follow grading system to assist Part D enrollees in selecting Part D plans.²¹ In describing the “Medication Adherence for Diabetes Medications” Star Rating Measure, CMS explained: “One of the most important ways you can manage your health is by taking your medication as directed. The plan, the doctor, and the

MEDICATION ADHERENCE-RELATED QUALITY MEASURES



1

**DIABETES
MEDICATIONS**



2

**HYPERTENSION
(RAS ANTAGONISTS)**



3

**CHOLESTEROL
(STATINS)**



member [beneficiary] can work together to find ways to help the member take their medication as directed.”²²

CMS recognizes that while there is evidence showing MTM can improve medication adherence, it notes that medication management services offered by Part D plans fall short of their potential to improve quality and reduce unnecessary medical expenditures, most likely due to misaligned financial incentives and regulatory constraints. For example, due to the siloed nature of the benefit, a Part D plan that invests resources in an adherence program that reduces other health care utilization, such as keeping patients out of a hospital, does not receive any of the savings generated by the adherence program. That financial gain accrues to taxpayers and the patient, which is good, but creates a disincentive for plans to invest in programs in the first place.

As part of continued efforts to ensure seniors get the most out of their medications, the Part D Enhanced MTM model test began on January 1, 2017. The pilot program, run by the CMS Center for Medicare and Medicaid Innovation (CMMI), will test new ways to invest in MTM services to optimize medication use and improve care coordination.²³

Many successful adherence programs require quality improvement metrics,²⁴ electronic prescribing,²⁵ shared savings,²⁶ patient-centered medical homes,²⁷ and quality guidelines to promote medication and care compliance.²⁸ Both the ACA and the Health Information Technology for Economic and Clinical Health (HITECH) laws create incentives to adopt technology and facilitate data sharing via electronic health records and other reporting systems that help facilitate the infrastructure necessary to facilitate medication adherence.

In the ACA, Congress added new exceptions to the beneficiary inducement statute that open the door to greater adherence management. The HHS Office of the Inspector General (OIG) recently observed that the exceptions “are intended to protect certain arrangements that offer beneficiaries incentives to engage in their wellness and treatment regimens or that improve or increase beneficiary access to care, including better care coordination.”²⁹

Despite these and other changes over the past decade, suboptimal medication use and nonadherence continue to plague the United States and require a focused commitment to unleash private sector innovation to help address the problem in federal programs.

¹⁷ Social Security Act § 1860D-4(C)(2)(B)(iii).

¹⁸ Congressional Budget Office. Offsetting Effects of Prescription Drug Use on Medicare’s Spending for Medical Services (November 2012). The CBO estimates that a 1% increase in the number of prescriptions filled by Medicare beneficiaries causes Medicare spending on medical services to fall by roughly one-fifth of 1%. This formula is conservative, and envisions, roughly, a 1:1 tradeoff in costs and savings.

¹⁹ Testimony of Jonathan Blum, then-Director of the Center for Medicare Management on Improving Quality, Lowering Costs: The Role of the Healthcare Delivery System before Committee on Health, Education, Labor and Pensions, United States Senate (November 10, 2011)

²⁰ Social Security Act § 1860D-4(C)(2)(C)(emphasis added).

²¹ CMS, Medicare Health & Drug Plan Quality and Performance Ratings 2013, 56-59, Part C & D Technical Notes (Draft, updated Sept. 3, 2014).

²² Id. at 56.

²³ CMS Part D Enhanced Medication Therapy Management Model: <https://innovation.cms.gov/initiatives/enhancedmtm/>

²⁴ See, e.g. ACA § 3013.

²⁵ The Health Information Technology for Economic and Clinical Health (HITECH) Act, enacted as part of the American Recovery and Reinvestment Act of 2009, promoted the adoption and meaningful use of health information technology, including e-prescribing.

²⁶ ACA § 3022.

²⁷ ACA §§ 2703, 3502.

²⁸ ACA § 1311(g)(1).

²⁹ 79 Fed. Reg. 59717, 59725 (Oct. 3, 2014).

MEDICATION MANAGEMENT PROGRAMS CAN SUPPORT ADHERENCE AND ACHIEVE SAVINGS

Patients are non-adherent for many reasons, including side effects associated with medicine, lack of insurance coverage, unaffordable cost sharing, forgetfulness, and low health literacy or lack of education or engagement.

Compelling evidence indicates that medication management programs can be cost effective in the right circumstances, though much depends on the patient populations being targeted as well as the mode of intervention. Not all drugs are equally effective in reducing medical costs across broad patient populations. Nor are all patients equally responsive to every medication management technique. An adherence program targeting 45-year olds taking statins for marginally high HDL (to inhibit arterial plaque buildup) may not generate a health system savings for many years. Conversely, interventions with high-risk patients can have an immediate impact on spending. One study, involving hypertensive patients, was found to reduce the average number of hospital days by 2.1 percent. Because the patient population targeted had high medical costs to begin with, net savings in hospital and emergency room usage averaged \$5,910 per patient where those patients had perfect adherence. (Slightly lower adherence rates generated less savings.)³⁰ In such populations, intensive medication management programs may be worth the investment.

Within the Medicare program, MTM is the most common intervention used to help patients manage their complex medication regimens. A 2013 review of MTM programs offered by different Part D prescription drug plans (PDP)

found that the impact of interventions aimed at COPD patients with two or more chronic conditions varied significantly across PDPs, with the effect on hospitalizations ranging from a per-patient cost increase of \$75 to a decrease of \$574.³¹

Health coaching programs, which target patients with poorly controlled chronic conditions, are another way to improve adherence.³² These programs supply trained coaches to help patients manage their chronic conditions via medication reconciliation, adherence counseling, and collaborative communication. Some modes of intervention are more effective than others. A “meta” review of cardiovascular medication adherence studies found that 38 percent of those involving interventions over the phone produced statistically significant improvements. On the other hand, face-to-face interventions by pharmacists had an 83 percent success rate.³³ A program that involved educating pharmacists, called “screening and brief intervention”, improved adherence by 3 to 5 percent, depending on the medication. Patients taking oral diabetes medications saw their 12-month health care costs decline by \$341, but those taking calcium channel blockers, a heart medication, had slightly higher 12-month costs.³⁴

The various types of medication management services offered around the United States are almost as diverse as differences in patients. To be cost effective, adherence program services should be targeted, tailored and flexible, to address the specific needs of the nonadherent patient population.

³⁰ Dragomir A, Cote R, Roy L, et al. Impact of adherence to antihypertensive agents on clinical outcomes and hospitalization costs. *Med Care*. 2010;48(5):418-425. See also: Center for Medicare and Medicaid Services, “Evidence Supporting Enhanced Medication Therapy Management”.



IMPROVED MEDICATION ADHERENCE CAN SUPPORT THE MOVE TO VALUE-BASED REIMBURSEMENT*

Value-based arrangements are new pricing or contracting models that tie reimbursement for medications to endpoints or patient outcomes, or otherwise reduce payer risk. Under these agreements, the final payment received by a pharmaceutical company for its medicine may depend on achieving mutually agreed-upon results such as improved patient outcomes, or avoidance of costlier medical services. Value-based contracts generally include certain features, such as specified patient populations, performance benchmarks, and how financial risks and rewards will be structured.

In value-based arrangements, proper medication adherence is critical to determine if the outcome is based on the effects of the medication- as opposed to a poor outcome resulting from nonadherence. Because these contracts often reduce pharmaceutical manufacturer payment if the clinical outcome target is not met, adherence programs can be an important component of the contract.



³¹ Perlroth D, Marrufo G, Montesinos A, et al. Medication Therapy Management in Chronically Ill Populations: Final Report. August 2013.

³² Thom, DH, Willard-Grace, R, et al. The impact of health coaching on medication adherence in patients with poorly controlled diabetes, hypertension, and/or hyperlipidemia: a randomized controlled trial. J Am Board Fam Med. 2015; 28(1):38-45

³³ Cutrona, S, Choudhry, N et al., Modes of Delivery for Interventions to Improve Cardiovascular Medication Adherence, The American Journal of Managed Care, vol 16, No. 12. December 2010

³⁴ Pringle, J., Boyer, B. et al., "The Pennsylvania Project: Pharmacist Intervention Improved Medication Adherence and Reduced Health Costs", Health Affairs. August 2014. ("...common medication adherence reminders, ill box provision, and targeted patient care management programs have had limited impact on an entire [Medicare Advantage] population's adherence...")

* Other terms that may refer to value-based reimbursement: results-based, outcomes-based, indication-based, pay-for-performance, per-member-per-month (PMPM), and/or regimen-based.

ANTI-KICKBACK STATUTE SAFE HARBORS PROTECT BENEFICIAL ARRANGEMENTS

The high medical costs associated with nonadherence, combined with growing evidence that well-targeted medication management programs can cost-effectively improve population health, raises the question of why there is not more of a focus on improving adherence. Economic incentives play a role—and at the margin, regulatory risk may tip the balance. Some of the more involved adherence programs—including Comprehensive Medication Management, adherence visualization technology, disease-specific health coaching, and coordination using EHR tools—are not generally employed in Medicare or Medicaid, in part, because of uncertainties created by the Anti-Kickback Statute and its lack of clarity around the legal status of medication adherence programs.

Over-vigilance carries risk, as when anti-kickback rules inadvertently penalize, through threat of civil, criminal, and/or administrative sanctions. These risks exist despite the benefit of arrangements that, when properly structured, pose only minimal risk of fraud and abuse. To reduce the risk that the broadly-worded Anti-Kickback Statute would thwart such beneficial arrangements, Congress empowered the OIG to

develop safe harbors to protect certain arrangements from criminal penalties, and also required OIG to request safe harbor proposals from the public each year.³⁵ As explained by OIG, “Since the statute on its face is so broad, concern has arisen among a number of healthcare providers that many relatively innocuous, or even beneficial, commercial arrangements are technically covered by the statute and are, therefore, subject to criminal prosecution.”³⁶

Safe harbors are thus intended to “limit the reach of the statute somewhat, by permitting certain non-abusive arrangements, while encouraging beneficial and innocuous arrangements.”³⁷ “[P]eriodic updating of this [safe harbor] regulation, with the opportunity for public input,” OIG has observed, is “the best way to ensure that these regulations remain practical and relevant in the face of changes in healthcare delivery and payment arrangements. The need to clarify, interpret, fine tune, expand, or otherwise alter this regulation in response to public and industry input will provide an occasion for us to respond to unanticipated, newly developing, or other beneficial arrangements.”³⁸

³⁵ Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100-93, § 14(a) (requiring HHS to develop safe harbors); 42 U.S.C. § 1320a-7d (requiring an annual solicitation seeking proposals from the public for new or modified safe harbors and Special Fraud Alerts). Even before the 1996 law requiring the annual solicitation for safe harbor proposals, OIG acknowledged the Congressional expectation that it should “formally re-evaluate the anti-kickback regulations on a periodic basis, and . . . solicit public comment at the outset of the review process.” Medicare and State Healthcare Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952 (July 29, 1991) (quoting H.R. Rep. No. 85, part 2, 100th Cong. 1st Sess. 27 (1987)).

³⁶ 56 Fed. Reg. 35952 (July 29, 1991).

³⁷ 78 Fed. Reg. 78807 (Dec. 27, 2013) (quoting 56 Fed. Reg. 35952 (July 29, 1991)).

³⁸ 56 Fed. Reg. 35952 (July 29, 1991) (emphasis added).

³⁹ 42 U.S.C. § 1320a-7d(a)(2).

⁴⁰ 81 Fed. Reg. 88368 (December 7, 2016)



As part of the law that requires OIG to solicit safe harbor proposals from the public on an annual basis, Congress required that, in evaluating proposals for new or modified safe harbors, OIG examine the extent to which the proposals would increase or decrease:



**ACCESS TO
HEALTHCARE
SERVICES**



**THE QUALITY OF
HEALTHCARE
SERVICES**



**PATIENT FREEDOM
OF CHOICE AMONG
HEALTHCARE
PROVIDERS**



**COMPETITION
AMONG
HEALTHCARE
PROVIDERS**



**COSTS TO
FEDERAL HEALTH
CARE PROGRAMS**



**THE POTENTIAL
OVERUTILIZATION
OF HEALTHCARE
SERVICES**



**THE ABILITY OF HEALTHCARE FACILITIES TO PROVIDE SERVICES IN MEDICALLY
UNDERSERVED AREAS OR TO MEDICALLY UNDERSERVED POPULATIONS ³⁹**

OIG exercised this authority most recently in 2016 by creating new safe harbors for, among other things, discounts on drugs furnished under the Medicare Coverage Gap Discount Program and free or local transportation services that meet specified criteria.⁴⁰ In total, the OIG has issued 28 regulatory safe harbors. Congress has also created 10 legislative exceptions to the AKS.

PROPOSAL FOR A NEW ADHERENCE SAFE HARBOR

There is a significant need for expanded medication adherence programs, particularly in Medicare and Medicaid, where the incidence of chronic disease is greater and the opportunity from improved adherence is more robust. Notably, the state of the art in medication management is still developing, with no silver bullet or one-size-fits-all solution to addressing nonadherence. The costs and benefits of adherence programs vary widely, depending on the nature of the intervention and the patient population being targeted.

In the interest of growing this knowledge base of how and when to intervene, providers, health plans, manufacturers, researchers, and other stakeholders should have the flexibility to test new ideas without the risk of criminal prosecution. While existing anti-kickback exceptions or safe harbors, such as the discount or personal services safe harbors, will protect many arrangements designed to improve adherence, none does so explicitly.⁴¹ This lack of certainty breeds an abundance of caution that favors inaction.

USE CASE

One issue in addressing medication non-adherence is the limited visibility providers and other healthcare professionals have into knowing if their patients fill and remain adherent to the therapies they prescribe for them. Company X developed a web-based tool that utilizes prescription claims data from pharmacies to address this problem. The data is imported and then used to run adherence calculations. A physician dashboard displays longitudinal adherence information to a health care professional for a given patient in a user friendly manner. The tool would display this data for all drugs prescribed to the patient, not just Company X's medications.

Given the value represented by the dashboard and its underlying data and software, Company X was not willing to make this tool available to the healthcare community without charge due to the lack of clarity regarding the application of the Anti-kickback statute and given the lack of guidance from the OIG on adherence programs. Company X considered selling the tool but has made a business decision to no longer invest in developing and commercializing the resource. Company X then explored the option of divesting the tool to a medical group, who is also interested in improving medication adherence. While the medical group was interested in the resource and its capabilities, it also cited anti-kickback challenges as preventing this partnership from moving forward.

⁴¹ For example, a manufacturer paying fair market value to a pharmacy for refill reminders could be protected by the personal services and management contracts safe harbor, assuming all other prongs of the safe harbor were satisfied.

⁴² For example, programming adherence messages into an electronic health record system may fall outside the EHR safe harbor in some circumstances and could potentially qualify for protection under the proposed adherence safe harbor.

⁴³ For purposes of the proposed safe harbor, consideration could be given regarding whether to include vaccines that are within the scope of a recommendation made by the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention, given the critically important role that adherence to these recommendations plays in preventing disease and containing public health risks.



Considering the many benefits and potential concerns, we propose the creation of a safe harbor under the AKS that is structurally consistent with existing safe harbors, and which incorporates safeguards to protect against the types of fraudulent and abusive practices about which OIG has historically expressed concern.

The proposed safe harbor would not affect the eligibility of an arrangement for any existing safe harbors or statutory exceptions, but could offer an opportunity to protect arrangements that may fall outside the scope of existing safe harbors.⁴² Generally speaking, it would protect any payment or nonmonetary remuneration consisting of items or services such as written or electronic materials, telephone calls, hardware, software, or information technology and training services that is intended to improve patient health by supporting patient adherence to a treatment regimen recommended by the patient's healthcare provider (including a regimen of preventive care). Financial support for these items and services would also be protected.⁴³ For example, adherence support would include disease state educational materials provided to patients to help them understand the importance of adhering to a physician's treatment regimen.⁴⁴

As outlined in Appendix I, the proposed safe harbor would protect adherence support arrangements only if they satisfy the following safeguards:

- 1** The adherence support is not designed to interfere with or undermine the independence of health care provider decision-making (e.g., provider decisions to change to a different treatment, to discontinue therapy, or otherwise to alter the treatment regimen).
- 2** If the adherence support involves an arrangement between entities (not including patients): The arrangement between the parties must be set forth in a written agreement signed by the parties that describes all material terms of the arrangement, including the role and responsibilities of and the payments or nonmonetary remuneration to be provided by each party. Additionally, the agreement must include terms requiring compliance with patient privacy laws, if applicable. Patients intended to benefit from the program would not be parties to this agreement.
- 3** Neither the eligibility of a party to participate in the arrangement nor the amount or nature of the adherence support is determined in a manner that takes into account the volume or value of referrals or other business generated between the parties, including:
 - a. Incentives that impact the total number of prescriptions, orders, administrations, etc. of a product by a party (so long as the total is calculated without regard to particular payers);
 - b. a party's ability to design, implement, or evaluate the adherence support; or
 - c. a per-unit payment metric (so long as that metric is determined in advance and set out in a writing that details the payment formula and prohibits any modifications during the period covered by the writing that take into account the volume or value of business generated between the parties).⁴⁵
- 4** If the adherence support involves communications to, or interactions with, patients or prescribers, each entity sponsoring and/or providing the adherence support must disclose its role to participating patients, or require such disclosure, in writing.

These parameters provide essential safeguards to protect against potential abuse while advancing better care through aligned incentives.

⁴⁴ An arrangement that provided this type of information was addressed and favorably evaluated by the OIG in Advisory Opinion No. 08-05.

⁴⁵ This provision is modeled on the electronic health record safe harbor, which similarly specifies certain factors that may be taken into account without running afoul of a safe harbor provision that bars arrangements based on the volume or value of referrals. See 42 C.F.R. § 1001.952(y)(5)(i)-(vii).



CONCLUSION

Nonadherence is perhaps America's most overlooked behavioral health crisis, an important public health element that makes our mortality and morbidity the highest in the developed world. The available evidence suggests that the social and economic costs of nonadherence are comparable to those associated with tobacco use—with potential direct medical costs to consumers and taxpayers totaling more than \$6 trillion over the next decade alone.

A growing body of medical literature and evidence suggests that this problem is treatable through cost-effective medication management interventions, and a number of pilot programs have shown remarkable success.

But there remains a lack of leadership in the field of medication management and adherence. This stems from two primary factors. First, there are inadequate incentives among traditional providers to practice preventative medicine. Second, rules aimed at discouraging inappropriate marketing by biopharmaceutical manufacturers are often interpreted in a way that confounds the establishment of new programs. Notably, the government does not conduct intensive medication management, making leadership by the private sector even more essential.

To address this problem, we propose the creation of a medication adherence regulatory safe harbor under the Anti-Kickback Statute. Our proposal would circumscribe relationships between entities, such as biopharmaceutical manufacturers and third parties—mainly adherence services vendors and pharmacists—to ensure that the remuneration does not interfere with clinical decision-making, lead to patient steering or encourage overutilization, but, rather, is focused on helping patients to follow their recommended treatment regimens correctly.

The current lack of clarity breeds an abundance of caution that favors inaction. At a time when our leaders are increasingly coalescing around how to lower health care costs, removing obstacles to addressing nonadherence is an effective and commonsense way to improve health and promote innovation that can ultimately increase quality and lower costs. Creating a safe harbor for adherence programs should be at the top of the agenda.

APPENDIX I

PROPOSED ADHERENCE SAFE HARBOR

42 C.F.R. § 1001.952(z)

Adherence Support. As used in section 1128B of the Act, “remuneration” does not include any payment, or nonmonetary remuneration (consisting of items and services such as written or electronic materials, telephone calls, hardware, software, or information technology and training services or financial support for the same), that is intended to improve patient health by supporting patient adherence to any treatment regimen recommended by the patient’s health care provider (hereinafter, “adherence support”), if all of the following conditions are met:

1

The adherence support is not designed to interfere with or undermine the independence of health care provider decision-making, including, for example, provider decisions to change to a different drug or other treatment regimen, to discontinue therapy, or to extend therapy beyond what has been recommended by the patient’s health care provider.

2

If the adherence support involves an arrangement between entities (other than individual patients):

i. The arrangement is set forth in a writing that:

A. Is signed by the parties to the arrangement;

B. Covers all material terms of the arrangement, including the roles and responsibilities of each party and the payments or nonmonetary remuneration, to be provided; and

C. Includes terms to require compliance with patient privacy laws, as applicable;

ii. Neither the eligibility of a party to participate in the arrangement, nor the amount or nature of the adherence support to be provided, is determined in a manner that takes into account the volume or value of referrals or other business generated between the parties; provided, however, that it shall be permissible for the party (or parties) to take into consideration any of the following factors in designing and administering the adherence support arrangement:

A. The total number of prescriptions, orders, administrations, dispenses, fittings, implantations or uses of a product (or products) by a party for which adherence support will be provided, so long as such total is calculated without regard to particular third party payors (including but not limited to federal health care programs); and

B. A party’s ability to design, implement, or evaluate the adherence support that is included in the arrangement; and

C. a per-unit payment metric (such as unit of time, unit of service, or unit of product), provided that the metric is determined in advance of payment and memorialized in writing that:

i. Sets forth the specific formula for the calculation in sufficient detail that conformity to the formula can be objectively verified; and

ii. Provides that the formula cannot be changed or modified during the time period covered by the writing in any manner that takes into account the volume or value of referrals or other business that is generated between the parties.



APPENDIX I

3

If the adherence support involves communications to, interactions with patients or prescribers, each entity sponsoring and/or providing the adherence support discloses its role to participating patients, or requires such disclosure, in writing.

Note to paragraph (z): An arrangement that meets the requirements of this paragraph (z) need not also meet the requirements of any other paragraph in this section; and, failure of an arrangement to meet the requirements of this paragraph does not preclude application of another paragraph in this section. Adherence support does not include the provision of discounts, rebates, or payments that directly impact the price of the health care provider-recommended treatment or product that is the subject of the adherence support.

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Prescriptions for a Healthy America

"A Partnership for Advancing Medication Adherence"

ABOUT THE AUTHOR

Prescriptions for a Healthy America: A Partnership for Advancing Medication Adherence (P4HA) was launched in 2013 by the Council for Affordable Health Coverage. P4HA brings together leading patient, physician and health care industry leaders to urge policymakers to implement near-term solutions that will help reduce health care costs and improve the lives of patients across the nation.

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