



REWARDING RESULTS

Moving Forward on Value-Based Contracting for Biopharmaceuticals

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I. EXECUTIVE SUMMARY

Introduction

The shift in US health care, from payment based on volume to payment based on value, has sparked interest among payers and pharmaceutical companies in new pricing and contracting arrangements for prescription drugs. The objective of these new arrangements is to reward pharmaceutical manufacturers for results, paying them for improved patient outcomes from successful use of drugs rather than paying them based on the volume of drugs sold.

A wide range of drugs could be covered through these arrangements. They vary from high-cost specialty pharmaceuticals to more conventional drugs for chronic conditions that account for large costs in health care. If properly executed, value-based contracts could align with important societal goals: better health of individuals and populations, better quality health care, and sustainable growth rates of health spending.

In November 2016, NEHI called upon a stakeholder group of payers, biopharmaceuticals companies, pharmacy benefit managers, and others to examine the opportunities for, and obstacles to, value based contracting. This white paper stemming from that convening provides background on value-based contracting for biopharmaceuticals, offers examples of the types of contracts are being struck, describes obstacles that either stand in the way of these contracts or makes them more difficult to execute, and sets forth recommendations for policy and other changes that could facilitate the broader use of these contracts in the future.



What are Value Based Contracts?

“Value-based contracting” is an umbrella term for a variety of purchasing strategies outside of traditional models of volume-based purchasing. Value-based contracts can take many forms, but common features include the following:

- Payment tied to achievement of goals, objectives, or performance benchmarks. This payment structure that may complement or even replace more traditional discounts and rebates that are based solely on the volume of product sold.
- Agreement on the particular population of patients that will be the focus of the contract – that is, on which patients will receive or have access to a drug, based on the best clinical evidence.
- Agreement on how results will be documented to prove that the contract’s goals, objectives, or performance benchmarks are achieved.
- Agreement between the contracting parties about how financial risks and rewards will be assigned or shared.

What are the challenges in value-based contracting?

Stakeholders convened by NEHI point to a series of obstacles that impede negotiation and execution of value-based contracts. Some of the obstacles are internal to payer and manufacturer organizations, since value-based contracting requires both types of organizations to adopt new ways of doing business. Other impediments to these contracts stem from existing laws and regulations put in place for other reasons, such as to guarantee that government programs get the best prices for drugs.

OPERATIONAL

Payers and manufacturers may have to undertake internal changes or overcome structural challenges to executing value-based contracts. These include the following:

- 1 *Defining appropriate goals, objectives, and performance benchmarks:*** Moving beyond simple contract parameters, such as the volume of drugs sold, to more complex ones such as improving patients' outcomes, may require more costly development of new types of measures.
- 2 *Data collection and analysis:*** Results of a drug's use among patients is proven through data collection and analysis. These activities create administrative complexity and cost not present in conventional contracts that link payment solely to the volume of drugs sold.
- 3 *Shorter versus longer time horizons:*** Biopharmaceutical manufacturers may not be able to demonstrate the full value of their products over the typical year-at-a-time period during which patients are covered by insurers. Insurers lack a clear financial incentive to cover drugs that may benefit patients who may switch their coverage periodically to new insurance providers.

REGULATORY

At present, federal regulations that guide enforcement of laws around drug purchases – both purchasing through Federal programs and those made by private, commercial payers – do not explicitly incorporate guidance regarding value-based contracts. This lack of explicit guidance creates a degree of uncertainty that inhibits negotiation and execution of value-based contracts. Challenges with current regulation include the following:

- 1 *Federal Health Program Drug Price Regulations:*** Current regulations generally guarantee that government health programs (Medicaid, the 340B Drug Discount Program, and the Medicare Part B program) are entitled to the single lowest price a manufacturer charges any purchaser at any point in time. This policy creates a disincentive for contracts such as money-back guarantee, in which a payer would pay nothing when a drug proves ineffective as used in individual patients.
- 2 *The Anti-Kickback Statute:*** Under current statute, some “pay for results” discounts negotiated under a value-based contract might be construed as an unlawful inducement to use a manufacturer's drug.
- 3 *U.S. Food and Drug Administration Regulation of Manufacturers' Communications with Payers:*** It is unclear whether some communications that may need to take place to execute certain value-based contracts would be allowed under current regulations. The FDA has proposed new regulatory guidance regarding exchange of health care economic information and on communication between manufacturers and payers before a drug is approved. Both are viewed as essential to negotiation of value-based contracting, but further FDA guidance will probably be needed.

How do we move forward with value-based contracting?

NEHI recommends the following to remove or reduce the barriers to value-based contracting, to improve patient outcomes, and to promote more sustainable rates of increase in health care spending.

OPERATIONAL

Various government and private, cross-sector initiatives could strengthen the capability of payers, manufacturers, and others to execute value-based contracts, including these:

- 1 *Continue development of health care quality and performance measures:*** The work of organizations focused on developing quality metrics (e.g. the National Quality Forum) should continue, with research priorities tied where possible to the need for innovation in pharmaceutical contracting.
- 2 *Invest in data infrastructure:*** Large national clinical data networks structured around common data formats and standards, such as PCORnet, the research network developed by the Patient Centered Outcomes Research Institute (PCORI), could streamline data collection essential to value-based contracts, and should be sustained.
- 3 *Continue to push for interoperability:*** Federal and cross-sector efforts to achieve reliable clinical data exchange and electronic health record interoperability should be continued.

REGULATORY

To address current challenges, changes and clarifications need to be made in regulation, as follows:

- 1 *Define value-based contracts:*** Stakeholders should reach consensus on a definition of value-based contracts eligible for appropriate regulatory forbearance in enforcement of federal law and regulation.
- 2 *Create flexibility under current pricing regulations:*** The Centers for Medicare & Medicaid Services should create appropriate flexibility within government pricing regulations to support value-based contracting found eligible for regulatory forbearance, such as money-back guarantees made by manufacturers to payers.
- 3 *Create a safe-harbor for value-based contracts within Anti-Kickback Statute enforcement:*** The U.S. Department of Health and Human Services' Office of the Inspector General should promulgate appropriate safe harbor protection under the Anti-Kickback Statute to allow manufacturers and health care payers to engage in qualified value-based contracts.
- 4 *Finalize communication guidelines:*** To encourage negotiation and execution of value-based contracts, the U.S. Food and Drug Administration should finalize guidance on communications between manufacturers and payers over economic information about drugs, including communication before these drugs are approved by FDA. The agency should also work with stakeholders to consider allowing some protections for similar communication about off-label drug uses.

FIGURE 1: VALUE BASED CONTRACTING: REWARDING RESULTS

THE STATUS QUO

Payers and Manufacturers Negotiate Discounts and Rebates - Regardless of How Drugs Are Used and Results They Achieve

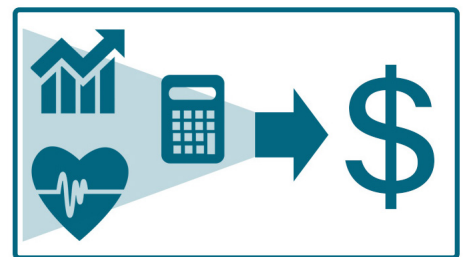
Purchasers (health plans, PBMs) pay manufacturers for drugs based on a unit price after reviewing evidence of safety and efficacy; through negotiations, manufacturers frequently agree to rebate funds to payers based on discounts for an increasing volume of drugs purchased.



AN ALTERNATIVE APPROACH

Payers and Manufacturers Negotiate Payment Based On How Drugs are Used and Results They Achieve

The range of potential goals, objectives and performance benchmarks for value-based contracting is wide:



PATIENT ADHERENCE

Payment linked to proof of medication adherence and persistence among targeted patient populations or patient sub-groups

CLINICAL BENCHMARKS

Payment linked to proof of –

- Population health (e.g. patient populations achieve specified goals such as blood pressure control or cholesterol control)
- Clinical Outcomes (e.g. improved rates of mortality, reduced rates of disability)

APPROPRIATE OR TARGETED USE

Payment varies depending on the disease or condition that a drug is used to treat

- Example: Indication-specific pricing (price of drug varies according to scientific evidence of its relative value in treating Disease A vs. Disease B)

AVOIDED HEALTH CARE COSTS

Payment linked to proof that use of drugs contributed to avoided illness and use of unnecessary medical services.

- Example: Avoided services (reductions in hospitalization, emergency department visits, etc.)
- Example: Control or reduction in total costs of health care (medical costs and prescription drug costs combined)

IMPACT ON THE OVERALL HEALTH CARE SYSTEM AND SOCIETY

Payment linked to proof that use of drugs contributed to improvements beyond patient care such as:

- Greater efficiency in the health care system (e.g. superior patient outcomes at lower costs)
- Social and fiscal goals (e.g. improvements in public health, lower costs of social services borne by federal, state and local governments)

II. VALUE-BASED CONTRACTING: WHAT IS IT?

For years, most pharmaceutical purchasing by health insurance plans and other payers has followed a traditional model. Health plans have paid either flat, unit-based prices for drugs or have paid on the basis of discounts negotiated with manufacturers, often with third-party prescription benefit managers (PBMs) negotiating on their behalf. Under these negotiated arrangements, manufacturers frequently agree to discounts that grow with the volume of sales. These result in “rebates” paid by manufacturers to insurers. The “discount-and-rebate” model applies widely in health care, including for most of the outpatient prescription drugs covered under health insurance pharmacy benefits. They also account for one half or more of drugs administered in clinics, hospitals, or physician practices, and typically are covered under insurance medical benefits.

In recent years, however, two trends have stimulated interest in alternatives to this traditional model of discount-and-rebate pricing and payment.

First, the US health care system is slowly shifting away from volume driven, “fee for service” payment to payment that takes into account the quality, cost effectiveness, and overall value of services provided to patients. There is a growing desire among payers and manufacturers to fashion similar value-based payment arrangements for drugs. Many payers believe they cannot ask providers such as physicians, hospitals, or health systems to take on financial risks for providing care to patients if the pharmaceuticals they prescribe patients aren’t also subject to value-based payment.

Second, the growing volume of high-cost therapies entering the market has put enormous pressure on payers and the health care system overall. A stunning 45 new active substances per year are likely to be launched through 2021.¹ Many of these therapies will be innovative, transformative in terms of their effectiveness in treating disease, and expensive. What’s more, the Food and Drug Administration’s (FDA) “breakthrough” therapy designation process means that many innovative drugs are also moving more quickly through the approval pipeline and into the market. Sixty percent or more of all new drugs approved by FDA receive some form of expedited review based on early evidence that the drugs address an important, unmet medical need, or provide patients with a superior alternative to existing therapies. Recently enacted legislation could enhance or accelerate expedited reviews even further.²



As a result, payers, providers, and programs including Medicare and Medicaid face the challenge of absorbing the cost of several new, high-priced drugs every year. As new drugs come onto the market relatively quickly, there is less than optimal understanding among clinicians and payers as to how they should best be put to use. Payers need to plan carefully for the introduction of these new therapies so that they can make them available to the appropriate pool of patients while still keeping premiums affordable. Payers are thus increasingly interested in learning what drugs are becoming available and how to use them most appropriately.

A result of all of these trends has been interest in “value-based contracting” – an umbrella term for a variety of purchasing strategies. Value-based contracts can take many forms, but common features include the following:

1. Payment tied to achievement of goals, objectives, or performance benchmarks that may complement or even replace traditional discounts and rebates that are based on the volume of product sold. Exhibit 1 illustrates several broad categories of these aims and benchmarks as identified by a group of stakeholders convened by NEHI.
2. Agreement on the particular population of patients that will be the focus of the contract and will receive or have access to a drug based on clinical evidence. In a variant of value-based contracting known as “indication-based pricing,” distinctions may also be drawn among various patient subpopulations in which use of the same drug may yield different positive results; for example, patients with melanoma versus patients with lung cancer.
3. Agreement on how results will be documented to prove that the contract’s goals, objectives or performance benchmarks are achieved.
4. Agreement between the contracting parties about how financial risks and rewards will be assigned or shared. At the simplest level, achieving good results from medication use in patients may result in a manufacturer having to pay lower rebates to a payer than would otherwise be the case. In more complicated arrangements, manufacturers might be able to earn bonuses or shared savings based on good results, or pay penalties for poor results, thus putting them more directly at financial risk. As detailed below, the ability of payers and manufacturers to execute contracts that share risks is based in part on whether they are permissible under federal law.

Payers are more willing to pay high prices if they can “pay for success”

Roughly 20 contracts with these features have been publicly disclosed in recent months (see Exhibit 2 below). Because these contracts are proprietary, a limited amount of detail is available about them, and information on outcomes and results may also be limited in the short-term. However, the appetite for these arrangements appears to be increasing. Although value-based contracting isn’t seen as a solution to the ongoing controversy over what constitutes optimal pricing of pharmaceuticals, it is understood by many manufacturers and payers as a form of private-sector regulation that can help them move past pricing disputes. In short, payers are more willing to pay high prices if they can “pay for success” – tying the net cost of drugs to evidence that therapeutic goals for patients are truly being achieved, and that other health costs may be reduced as a result.

FIGURE 2: Examples of Publicly-Disclosed Value-Based Contracts for Pharmaceuticals

DRUG <i>and indication</i>	MANUFACTURER PAYER	TERMS
Enbrel <i>rheumatoid arthritis</i>	Amgen HPHC	Harvard Pilgrim Health Care (HPHC) pays Amgen according to an overall measure of whether HPHC members achieve six goals, including, including patient adherence; patients inject medication every other week. ³
Entresto <i>congestive heart failure</i>	Novartis Aetna, Cigna, HPHC	Novartis agrees to pay additional rebates, depending on whether hospitalizations of patients for congestive heart failure are reduced, and the overall savings to payer. ⁴
Forteo <i>osteoporosis</i>	Eli Lilly HPHC	Lilly will reduce the price of the drug if improvements are seen in medication persistence (more patients injecting medication as they should, daily). HPHC and Eli Lilly agreed to work together, with HPHC’s pharmacy network, to improve patient persistence. ⁵
Harvoni <i>Hepatitis C</i>	Gilead Sciences Cigna	Cigna agrees to include Harvoni as the only preferred brand prescription drug treatment for customers with hepatitis C genotype 1. Terms of the agreement are not disclosed but the agreement includes development of an “innovative outcomes incentive alignment” based on actual therapeutic response to treatment across Cigna’s customer population. ⁶
Januvia and Janumet <i>diabetes</i>	Merck Aetna	Merck agrees to pay a rebate on Januvia and Janumet based in part on those products’ contributions to helping Aetna’s commercial member population with type 2 diabetes achieve or maintain treatment objectives. ⁷
Praluent <i>hypercholesterolemia</i>	Sanofi Cigna	Sanofi agrees to modify the price of the drug based on how well customers respond to the medications, as demonstrated by a reduction in levels of low-density lipoprotein cholesterol. ⁸
Repatha <i>hypercholesterolemia</i>	Amgen Cigna, HPHC	Amgen agrees to modify the cost of the drug based on how well customers respond to the medications, as demonstrated by a reduction in levels of low-density lipoprotein cholesterol. ⁹
Sovaldi and Harvoni <i>Hepatitis C</i>	Gilead Sciences Catamaran (PBM)	Catamaran (now Optum Rx) agrees to offer Sovaldi and Harvoni as exclusive treatments on special drug formularies that clients (health insurers) may elect to utilize. Patients’ adherence is monitored through specialty pharmacy services, allowing client health insurers to “take into account clinical results” in calculating overall treatment costs. ¹⁰
Trulicity <i>diabetes</i>	Eli Lilly HPHC	Harvard Pilgrim places Trulicity on its preferred drug formulary, but will pay a lower net price to Eli Lilly if fewer of its members reach a preferred endpoint (HbA1c less than 8%) as compared to individuals taking other GLP-1 receptor agonists, and a higher net price if patients taking Trulicity achieve lower HbA1c levels than patients taking competing drugs. ¹¹

III. BARRIERS THAT IMPEDE GROWTH AND INNOVATION IN VALUE-BASED CONTRACTING

The stakeholders convened by NEHI point to a series of obstacles that impede negotiation and execution of value-based contracts. Some of the obstacles are internal to payer and manufacturer organizations, since value-based contracting requires both types of organizations to adopt new ways of doing business, as detailed below. Although some parties to these contracts believe that they are overcoming these operational hurdles, others still consider them challenging.

Other impediments to these contracts stem from laws and regulations originally put in place to protect public finances and public health, but whose structure and substance inadvertently create obstacles. Examples include the federal Anti-Kickback Statute that prevents vendors from steering health insurers, physicians, or hospitals to use of drugs, devices, and other products by offering inappropriate payments or inducements. Nearly all of these laws and regulations were written with traditional fee-for-service transactions in mind, and not for the value-based contracts that manufacturers and payers are exploring today. The challenge for policymakers is to adapt these laws and regulations so that they continue to protect the public interest, but also allow for appropriate forms of value-based contracting – especially those that result in improved outcomes for patients and lower costs for the health care system as a whole.

OPERATIONAL BARRIERS

As noted above, a value-based contract requires a payer and manufacturer not only to document the volume of products sold, but also to document proof that goals, objectives, and performance benchmarks have been achieved. For many payers and manufacturers, these expanded contract terms are new. Some organizations actively engaged in value-based contracts believe that their growing experience is reducing the time and expense of administering them. However, operationalizing value-based contracts still requires investment, especially in data collection and analysis. A number of these operational barriers are described below.

1. Goals, Objectives, and Performance Benchmarks

As noted above, value-based contracts may hinge on a range of performance indicators, from comparatively straightforward to more complex. For example, several current contracts for new PCSK-9 inhibitor drugs (used to treat persistently high levels of cholesterol stemming from Familial Hypercholesterolemia) utilize well-accepted and routinely reported measures of cholesterol gleaned from standard laboratory tests. But appropriate outcome measures - or “endpoints” - for other innovative drugs are likely to be more esoteric. Manufacturers of innovative multiple sclerosis therapies, for example, have executed contracts with payers that entail collection of data on patient medication adherence, documentation of relapse-free periods, reductions in emergency room visits and hospitalizations, and reductions in overall health care utilization and costs for individual patients.

In the future, value-based contracts for various drugs may also encompass non-traditional metrics, such as patient-reported outcomes measures. To date, no publicly-reported value-based contracts have included the measure of goals to be achieved. Patient-reported outcomes are increasingly seen as relevant to both patient satisfaction and to tracking treatment effectiveness in conditions such as cancer, multiple sclerosis, chronic obstructive pulmonary disease, and rheumatoid arthritis. In these conditions, where total costs of care may be high and may persist for years, patient-centered and patient-reported outcomes measures may be essential to tracking care that meets the patient’s needs and preferences, and may be also essential to appropriate utilization of cost-effective care.

2. Data collection and analysis:

In addition to agreeing on goals and objectives in a value-based contract, parties must agree on sources of data and the means of analysis for documenting achievement of these aims. For example, both manufacturers and payers frequently cite assurance of patient medication adherence as a feature of value-based contracts requiring collection and analysis of pharmacy claims data.

Many also cite the growing ability to use various forms of “real world evidence” to “pay for results” by linking payments to manufacturers to proof of outcomes among patients. Such information typically becomes available after a drug comes on the market, is prescribed and dispensed by large groups of providers, and is used by larger groups of patients outside the context of the randomized clinical trials that precede a drug’s approval. A payer, such as a health plan, may want to see how its own enrollees fare on a drug, or may want to see results from repositories of “real world” data, such as patient registries or clinical data mined from the electronic health records of health care delivery systems.

In a relatively simple example, a payer may want to link payment to evidence that use of a new drug to combat congestive heart failure reduces costly hospitalizations among patients. In this case, hospitalization claims data that is routinely submitted to the payer can be matched against pharmacy claims data that is also routinely available. However, in the case of medicines, the agreed-upon measure may require data not ordinarily found in claims data, or may require integration of data from separate datasets or data sources. For example, some innovative new medicines to treat diabetes now promise to meet several clinical goals, such as reduction in blood glucose levels and cardiovascular risks. Verifying these effects on patients may require access to laboratory results that are not consistently available to the payer.

In these cases in which more and different data sources are needed to document complex goals, payers and manufacturers must agree upon a plan for collecting, integrating, and analyzing the data, as well as who will be responsible for analysis, how these tasks will be paid for, and by whom. All these factors add a degree of administrative complexity not found in more typical payer-manufacturer negotiations over prices and rebates that are linked solely to the volume of drugs that the manufacturer sells to the payer.

In these cases in which more and different data sources are needed to document complex goals, payers and manufacturers must agree upon a plan for collecting, integrating, and analyzing the data

3. Shorter versus longer time horizons:

The full value of many pharmaceuticals, whether older or newer drugs, is often only realized over a longer period than the one-year enrollment that consumers are guaranteed under state and federal insurance laws. For example, a drug may promise patients and payers the benefit of reduced hospitalizations, but these reductions may only occur in significant numbers as patients use the drug over a period of years. In such cases, a value-based contract may only make sense if it covers this longer time frame, and the payer and manufacturer agree to adjust rebates periodically over a multi-year contract. The longer time frame may be necessary even given the fact that some patients will disenroll from coverage from one year to the next, moving on to become enrolled under another health plan.

Linking several years' worth of results to what could be multiple revisions in payments adds yet another level of operational complexity to value-based contracts, and could trigger multiple provisions of state and federal regulations described below.

REGULATORY BARRIERS

Several areas of federal law govern the purchase and sale of pharmaceuticals. These statutes and regulations pertain to drug purchases made by, or on behalf of, government-sponsored programs such as Medicare and Medicaid, as well as those made by private, commercial purchasers such as health plans.

At present, federal regulations that guide enforcement of these laws do not explicitly incorporate guidance regarding value-based contracts. Recently a number of these contracts have been struck as payers, manufacturers and federal authorities conclude that they are consistent with federal law. Nevertheless, NEHI's stakeholder group concluded that lack of more explicit guidance stands in the way of more execution of value-based contracts. Chief issues are drug price regulations pertaining to government health programs such as Medicaid; regulations under the federal Anti-Kickback Statute [42 U.S.C. § 1320a-7b]; and the U.S. Food and Drug Administration (FDA) regulation of manufacturer communication and exchange of data and information with payers.

1. Government Health Program Drug Price Regulations

All federal and federal-state programs that purchase, subsidize, or otherwise regulate drug purchasing are governed by extraordinarily complex sets of regulations. The NEHI stakeholder group identified regulations within several programs that could be adapted to encourage appropriate forms of value-based contracts for pharmaceuticals.

a) Medicaid Best Price Regulation: Under federal law governing the Medicaid Drug Rebate Program, state Medicaid programs are eligible for quarterly rebates from manufacturers on each drug they cover. These rebates are determined on a per-unit basis, such as per-pill or per-capsule, and are classified as a Unit Rebate Amount (URA). The URA is calculated as manufacturers report two prices to the federal government; an Average Manufacturer Price (AMP), which is an average list price reported monthly and quarterly, and a Best Price that corresponds to the lowest price paid by any single commercial purchaser, also reported quarterly. The URA is calculated according to one of two options, whichever is higher; either a 23.1 percent discount from the AMP, or a discount equal to AMP minus the latest Best Price. Additional rebates are owed by the manufacturer if the AMP rises faster

than the Consumer Price Index. In essence, Medicaid programs receive the lowest price received by any commercial purchaser, net of rebates.¹²

In practice, the Best Price regulation means that any discount offered by a manufacturer to any commercial purchaser that is higher than 23.1 percent off the AMP — a size of discount that industry statistics indicate is common — results in an even larger discount to state Medicaid programs. As a result, the Best Price regulation creates a unique set of challenges for value-based purchasing arrangements that could prove counterproductive for both manufacturers and payers.

Consider the following example: A manufacturer and a commercial payer enter into a value-based contract that adjusts rebates from the manufacturer to the payer based on patient response to a drug. Higher rebates are available in cases in which patients do not respond, while lower rebates would apply in cases in which patients do respond to the therapy. Under current Medicaid Best Price rules that dictate how manufacturers calculate Best Price, manufacturers would be required to provide the drug in question to all state Medicaid programs with the highest rebate available to the commercial payer — in this case, the rebates offered for non-responders — regardless of whether any individual Medicaid beneficiary responded to the therapy. This potential cascade of rebates could render the value-based contract unprofitable or impractical for the manufacturer. This example would be further complicated by a value-based contract that adjusted and paid out rebates over multiple years as the drug's impact on patients' health, and on total health care costs, became clearer.

Under current regulation, a potential cascade of rebates could render the value-based contract unprofitable or impractical for the manufacturer

Alternatively, consider the hypothetical case of a “money-back guarantee.” In this type of value-based contract, the payer would not pay the manufacturer if a patient's use of a drug does not result in agreed-upon goals, such as lower blood glucose levels for a diabetes patient. Thus, the payer would only pay for the drug when it is effective. However, under existing Medicaid Best Price rule, the payer's non-payment could be considered a price of zero. In theory, this reality could compel manufacturers to provide the drug for free to all Medicaid programs, regardless of whether the therapy was effective for an individual Medicaid patient. Given this level of risk and uncertainty, manufacturers would understandably avoid such contracts unless they could be sure the Medicaid Best Price rule would not apply.

b) The 340B Drug Discount Program: The objective of the 340B program is to provide health care providers who serve vulnerable patient populations, such as low income or uninsured patients, with access to pharmaceuticals at low cost. Providers that are “covered entities” under the 340B program include more than ten categories of hospitals and clinics — in effect, more than one third of all U.S. hospitals—that provide health care to low-income and indigent patients.¹³ They purchase drugs at a ceiling price set in a manner similar to the Medicaid Best Price method. In much the same way that provisions of value-based contracts could trigger compulsory price reductions under the Medicaid Best Price rule, so too could they trigger comparable reductions in the 340B program, forcing prices paid by covered entities even further downward.

c) Medicare Part B Drug Reimbursement: Under the Medicare Part B program, physicians are entitled to dispense necessary medications directly and bill Medicare for the cost of the drugs along with a six percent markup to cover practice expenses (often referred to as “buy and bill”). Medicare reimburses physicians and other providers at a defined Average Sales Price (ASP), an average manufacturer sales price net of rebates, discounts, and other price concessions made by manufacturers plus the six percent mark-up.¹⁴

A value-based contract that a commercial payer may strike with a drug manufacturer outside the Medicare Part B program could still have a direct effect on reimbursements made to physicians and other providers under the Medicare Part B program. Prices agreed to in a value-based contract for prescription drugs (a contract for drugs not purchased directly by a physician or other provider) would still factor into calculation of the ASP for purposes of Part B reimbursement to providers. Value-based contracts also pose a timing problem for Part B providers. Manufacturers must calculate the ASP for a drug every quarter and report it to the federal government, which then updates the ASP with a two quarter lag. Thus, a provider might pay one price for a drug, only to be reimbursed by the Part B program later at a lower level than expected if, in the interim, the ASP is driven down by value-based contracting in the commercial sector.

d) Pricing Revisions and Re-Statements: Manufacturers are required to file regular reports with the federal health programs on the prices paid for their products throughout the U.S. health care marketplace. The prices and discounts that manufacturers offer to government and commercial payers must be revised and restated as they change. Manufacturers who fail to keep up this reporting, or who find themselves in dispute with enforcement authorities, can be found liable for penalties. To the extent that value-based contracts may add further complexity to price reporting, and thus to risk, when manufacturers otherwise act in good faith, then appropriate protections may be necessary for manufacturers who enter into value-based contracts that are in the public interest. (Standards for appropriate contracts are suggested in the Recommendations section below.)

2. The Federal Anti-Kickback Statute

The Federal Anti-Kickback Statute (42 U.S.C. Sec 1320a-7b) is a criminal statute that prohibits the exchange (or the offer of exchange) of anything of value in an effort to induce or reward the referral of federal health care program business, including business with the Medicare and Medicaid programs. Permissible, “safe harbored” activities can be defined by the statute or in implementing regulations issued by the Inspector General of the U.S. Department of Health and Human Services.

To date, neither Congress nor the HHS Inspector General has taken action to define value-based arrangements among manufacturers and payers that may be permissible under the Anti-Kickback Statute. Without explicit guidance on permissible activities and transactions that afforded them greater legal certainty, payers and manufacturers may be less likely to enter into these arrangements.

Consider the hypothetical example of a payer that offers prescription drug coverage through a Medicare Part D plan or a Medicare Advantage plan. If this payer executed a value-based contract with a manufacturer, the “pay for results” discounts negotiated under the contract could constitute an unlawful inducement to use the manufacturer’s drug. Alternatively, a clearly-defined safe harbor under the Anti-Kickback Statute would protect the payer and manufacturer, provided that the value-based contract

were drafted clearly and carefully to otherwise meet the terms of the safe harbor.

Similar uncertainty surrounds other aspects of potential value-based contracts. For example, if a manufacturer agreed to pay for all or some of the cost of data collection necessary to support a value-based contract, this aspect of the agreement could also constitute an unlawful inducement under the Anti-Kickback Statute unless protected by a safe harbor.

The increasing number of publicly reported value-based contracts is proof that some payers and manufacturers are satisfied that they have been able to execute at least these value-based contracts in full compliance with the Anti-Kickback Statute. Still, these announced contracts are still comparatively few in number, and have been executed by a relative few payers and manufacturers. Appropriate protection under the Anti-Kickback Statute may be needed to expand the number of parties willing to take on value-based contracts and to create innovative contracting models.

3. Food and Drug Administration Regulation of Manufacturers' Communication with Payers

Under law, the U.S. Food and Drug Administration is charged with reviewing and approving applications for new drugs, and new uses for previously approved drugs, on the basis of their safety and efficacy. FDA is also charged with regulating the promotion and marketing of drugs so that they are not used unsafely or in an inappropriate manner by prescribers and patients. With some exceptions, manufacturers may only market, promote, and communicate information about a drug that is consistent with the approved or cleared uses of the product spelled out in the drug's "label," or package insert.

Manufacturers' communications with payers constitute a limited exception to this general rule, because FDA allows manufacturers to respond to "unsolicited" requests from payers for information that may not otherwise be included on the drug's label or package insert. For example, a payer may want to know whether the manufacturer has any information about how use of its drug compares to another form of treatment. To prevent this information from being used as a form of promotion, FDA expects that communication over such matters will be conducted solely between the manufacturer and the payer. For this reason, some payers and manufacturers employ the Academy of Managed Care Pharmacy's "e-Dossier," an online service through which payers may ask questions of manufacturers, and manufacturers may respond through a secure channel that cannot be accessed by prescribers and patients.

Health plans and prescription benefit managers are increasingly interested in evaluating data on the likely use and performance of new drugs before the drugs are approved and launched

Manufacturers have long sought greater ability to communicate proactively with payers about scientific evidence relative to both approved (on label) and unapproved (off-label) uses of pharmaceuticals. Meanwhile, payers among NEHI's stakeholder group suggested that health plans and prescription benefit managers are increasingly interested in evaluating data on the likely use and performance of new drugs before the drugs are approved and launched in the U.S. health care marketplace.

Under provisions of the Affordable Care Act and many state insurance laws, health insurers must submit their proposed rates for health insurance premiums to regulators six months to a year before the rates go into effect with a new health plan year. Internal planning by the health insurers must begin months in advance of this submission date. Payers are less able to budget and plan adequately for the coverage of new drugs if key information is only available at a point when budgets and insurance premium rates are set or nearly locked into place by insurance regulators.

Payers are less able to budget and plan adequately for the coverage of new drugs if key information is only available at a point when budgets and insurance premium rates are set.

The growing interest in paying for results seems likely to create more shared interest among manufacturers and payers in the exchange of information on new pharmaceuticals. Four issues are seen as central, as follows:

- Authority for manufacturers to communicate with payers about health care economic information (HCEI), or information encompassing the clinical qualities of a new therapy, as well as data on actual patients' responses to the therapy, its costs, and comparisons to alternative treatments;
- Greater authority for manufacturers to communicate on an unsolicited basis (proactively) with payers;
- Authority for manufacturers to communicate with payers before a drug is approved, to allow for earlier evaluation and planning by payers, and to create opportunities for more innovative value-based contracts;
- Authority for, or limited safe harbor protection of, manufacturer communication to payers of information on unapproved, "off-label" uses of a drug.

Draft guidance that FDA issued in January 2017 — on manufacturers' communication with "payers, formulary committees, and similar entities" — is likely to address at least some of these issues. The draft guidance offers detailed definitions designed to clarify longstanding uncertainties over what types of information manufacturers can communicate to these entities. It also clarifies that manufacturers may make such information available proactively to these entities, and may do so even before drugs are approved. Although the guidance is not expressly directed at value-based contracting, it is directed at manufacturers' contacts with entities that conduct "drug selection, (and) formulary management," and make "coverage/reimbursement decisions on a population basis for health care organizations."¹⁵ These categories are broad enough that they would appear to govern communications undertaken in the course of negotiating and executing value-based contracting between manufacturers and payers.

In effect, the draft guidance suggests a new immunity from liability for manufacturers that provide scientific evidence and other information that meet FDA's proposed standards. Whereas before, such communication would have been considered impermissible, and may have triggered penalties from FDA, a new safe harbor would now exist. This safe harbor would allow the types of two-way communications between manufacturers and payers, before a drug is approved, that should facilitate value-based contracting.

The public comment period on FDA’s draft guidance is open until mid-April 2017, and payers, manufacturers, and other stakeholder groups are expected to offer detailed responses. It is widely expected that FDA will ultimately make most or all of the draft guidance permanent, and thus approve the types of expanded communications between manufacturers and payers that should facilitate value-based contracting.

Communication about “off-label” drug uses and value-based contracts: It should be underscored that the efforts to expand allowed communications between payers and manufacturers noted above pertain only to uses of drugs that are approved or likely to be approved. An entirely separate area is communication about “off-label,” or unapproved, uses of drugs.

Under existing laws and regulations, manufacturers are largely prohibited from promoting drugs for unapproved or off-label uses. A detailed memorandum that FDA published in January 2017 reiterated a number of the agency’s long-standing concerns in this area.¹⁶ In particular, FDA fears that allowing more communication about off-label uses would make it less likely that manufacturers would conduct the rigorous clinical trials needed to gain FDA approval of these uses. Thus, for now, it appears unlikely that FDA will allow expanded communications between manufacturers and payers about off-label uses.

The practical effect is that any communications between manufacturers and payers about value-based contracting around off-label drug uses are proscribed. At present, the proscription poses little problem; all current value-based contracts pertain only to approved drug uses. Furthermore, since FDA considers all contracts between manufacturers and payers to be “promotional,” all contract terms must relate directly to the on-label, FDA approved use of a drug.

It is conceivable that this de facto bar to most off-label communication between manufacturers and payers could inhibit some forms of value-based contracting over time. In cancer therapies in particular, new drugs approved for certain cancers are frequently used off-label by clinicians to treat other cancers, often successfully. Payers anticipate that some drugs are likely to be used off-label, and thus have an interest in advance information that will guide their decision-making. Restrictions on off-label communication may inhibit experimentation with value-based contracting that might otherwise ensure appropriate patient access to therapy and prove valuable to patients and payers alike

.IV. RECOMMENDATIONS

Reducing or removing the barriers to value-based contracting will not be simple. As noted above, some obstacles are operational, and will require manufacturers and payers holding themselves accountable to make appropriate investments in time, expertise, data collection, and analysis. Other obstacles will require statutory or regulatory changes.

OPERATIONAL RECOMMENDATIONS

Organizations active in value-based contracting have moved steadily up a learning curve that is accelerating their receptivity to value-based contracts, and stimulating interest among other payers, providers, and health systems as well. But various government and private, cross-sector initiatives could

strengthen the capability of payers, manufacturers, and others to execute value-based contracts. Some examples include the following:

1. Measure Development

Value-based contracts hinge on agreement between payers and manufacturers on goals, objectives, and performance benchmarks that can be reliably evaluated, ideally through data that is collected routinely in the form of insurance claims, electronic health records, and other means. Several major organizations focus on development and use of such validated measures, and their work should be supported. The National Quality Forum promotes consensus-based endorsement of a wide range of validated measures of health care. The Patient Centered Outcomes Research Institute (PCORI) has expanded the field of patient-centered outcomes research, which provides a scientific basis for generating patient-centered outcomes measures, including patient-reported measures. Because these types of measures can serve as performance benchmarks in value-based contracts. The work of these and related organizations should continue, linking some of their work to the types of measurement that could be useful in value-based contracting.

2. Data Infrastructure

Value-based contracts can also hinge on the ability to quickly and accurately assess the state of “real world evidence” through analysis of electronic health records. Large national clinical data networks, such as PCORI’s PCORnet, structured around common data formats and standards, should be sustained.

3. Electronic Health Record Interoperability

Continued federal and cross-sector efforts to achieve reliable clinical data exchange and electronic health record interoperability will be a key factor in making “real world data” more accessible and useful to manufacturers and payers undertaking value-based contracts.

POLICY RECOMMENDATIONS

1. *All Stakeholders*: Define value-based contracts that will be eligible for protection under federal policy

Stakeholders should work collaboratively and with policymakers to identify a basic definition of value-based contracts, or the minimum elements that constitute a value-based contract. This common definition should become a standard against which pertinent federal laws and regulations should be reviewed and amended through creation of safe harbors, permitting eligible contracts between manufacturers and payers.

Stakeholders in the NEHI discussions generally agreed that a number of federal health care policies, rules, and regulations must be revised before payers and manufacturers engage more broadly in value-based contracting. The first priority should be achieving consensus among stakeholders and policy-makers as to the features and objectives of value-based contracts that federal policy should protect and encourage.

Such consensus should be formed around at least three issues.

Patients

First, because patients' health is paramount, every value-based contract should reward positive results for patients through optimal use of therapies, and serve fundamental national goals for improving health. Strategies to reach this goal may take many different forms. Federal policy should encourage a broad set of goals, objectives and performance benchmarks. Several broad categories of results are shown in Exhibit 1. Additional goals of import to patients could include the following:

- **Transparency to the patient:** Payers and manufacturers should make reasonable efforts to make patients aware of value-based contracts and how these contracts may influence their care and their choices for therapy.
- **Patient access:** Value-based contracts should enhance patients' access to innovative therapy, and support patients' ability to purchase therapies and continue treatment over time.

Health care improvements

Second, value-based contracts should support efforts to improve the quality and efficiency of the U.S. health care system. Specific goals in this category could be as follows:

- **Supporting excellence in clinical judgment:** Contracts should support the clinical judgments of clinician/prescribers and the goal of achieving care for the "right" patient, with the "right" medicine, at the "right" time.
- **Sustainability in health care spending and stability of health insurance markets:** Value-based contracts can and should serve the goal of helping payers and providers manage overall health care costs as new drugs come on the market.^a National policies on value-based contracting should also support efforts to improve the quality and efficiency of the U.S. Health care system as a whole, while fostering continued biopharmaceutical innovation. When possible, value-based contracting should also address larger social needs outside the health care system, such as maintaining the ability of elder residents to live at home and avoid nursing home placements.
- **Alignment with new payment models:** Contracts should be consistent with the expanding number of alternative payment models that reward providers for achieving superior patient outcomes. This goal is especially important if expedited drug approvals at FDA accelerate further. For example, FDA designation of a drug candidate as a "Breakthrough Therapy" could act as a trigger, prompting payers to make early contact with the drug developer in an effort to understand what the implications of the drug's approval might be using particular payment models.

Ancillary services

Third, federal policy should make appropriate accommodation for supportive, ancillary, or "wraparound" services that may be necessary to execute value-based contracts successfully. For example, assured levels of patient medication adherence will be crucial to the execution of many contracts. Carefully crafted safe harbor protection for manufacturer-payer partnerships on adherence supports, such as motivation counseling or periodic medication reviews by a clinical pharmacist, will facilitate value-based contracting, as will similar protection for services such as data collection and analysis.

a. This requirement would be in keeping with the traditional stance of the Office of the Inspector General at the US Department of Health and Human Services, which has directed that any exemptions from federal health program law must result in no net increase in federal spending at a minimum.

2. Centers for Medicare and Medicaid Services: Create appropriate flexibility within federal pricing regulations to support value-based contracting, and launch a parallel effort to expand value-based contracting in Medicaid

CMS should make a reasonable accommodation to the Best Price Rule of the Medicaid Drug Rebate Program so that payers and manufacturers may enter into “money back guarantee” contracts that return money to the payer when individual patients do not respond to a drug.

More broadly, CMS should provide flexibility with regard to the Best Price Rule for value-based contracts that meet core criteria as recommended above. Flexible Best Price policy could be tested through pilot projects to better understand the type of flexibility needed, and to refine CMS policy-making over time.

CMS should launch a parallel effort to encourage experimentation among state Medicaid programs and Medicaid managed care organizations with innovations in value-based contracting.

As NEHI’s stakeholder group pointed out, a money-back guarantee is perhaps the most straightforward value-based arrangement manufacturers could offer payers. Under a money-back guarantee, manufacturers would rebate the cost of therapy administered to individual patients who show no benefit from the therapy.

Currently, the Medicaid Best Price Rule inhibits negotiation of money-back guarantees, since the rule could be construed to trigger a 100 percent rebate to all purchasers of the drug. A reasonable adjustment to the rule – such as exempting cases of non-response from the Best Price calculation or adjusting the standard 23.1 percent minimum rebate – could facilitate money-back guarantee contracts.

Any change in administration of the Best Price Rule will have some impact on Medicaid programs. For this reason, new and flexible policy on the rule, designed to encourage commercial value-based contracts that meet core criteria, should still be tested to determine if new policy is both effective in allowing innovative contracting and in protecting Medicaid programs.

Any change in administration of the Best Price Rule will have some impact on Medicaid programs. For this reason, new and flexible policy should still be tested

At the same time, it is conceivable that Medicaid programs may benefit from experimenting with value-based contracts for pharmaceuticals. In fact, CMS and some state health policy makers have signaled just such a desire, particularly as many state Medicaid programs shift more beneficiaries into managed care organizations, and some states move Medicaid provider payments into alternative payment models. At present, CMS encourages value-based contracting between manufacturers and state Medicaid agencies, but only in the context of determining supplemental rebates to states that are paid in addition to those owed under the Best Price Rule. However, in July 2016, CMS signaled that it might go further – encouraging manufacturers to consult with the agency about the potential impact of any given value-based contract on subsequent Best Price calculations and their ultimate rebate obligations to Medicaid.¹⁷ CMS promised ongoing guidance on the issues.

In the interim, the National Academy of State Health Policy, the National Association of Medicaid Directors, and Medicaid Health Plans of America, have all urged CMS to create greater flexibility for Medicaid programs to enter into value-based contracting arrangements with manufacturers.¹⁸ A project of the John and Laura Arnold Foundation at the Oregon Health and Science University Center for Evidence-Based Policy now aims to recruit several state Medicaid programs to demonstrate value-based contracting in Medicaid.¹⁹

To facilitate broader exploration of value-based contracts, CMS should consider a comprehensive approach that might include the following actions:

- Collaboration with diverse stakeholders to identify and adopt a consensus definition of value-based contracts and core criteria as described above. This consensus definition should guide subsequent revision to federal price reporting requirements that currently inhibit value-based contracting in the commercial sector and could provide needed guidance for innovative contracting in Medicaid and other federal programs.
- Request for stakeholder comments on value-based contracting in Medicaid. This request could include stakeholder recommendations for CMS assistance that will enable state Medicaid programs to overcome the operational hurdles to value-based contracting. CMS could also invite recommendations on how value-based contracts executed by Medicaid programs and Medicaid managed care organizations could benefit from carefully-defined and appropriate manufacturer-supported goods and services, subject to appropriate safe harbor protections under the Anti-Kickback Statute.
- Sponsorship or endorsement of pilot projects in value-based contracting in both the commercial sector and in Medicaid programs, designed to test refinements in policy that will support contracts that meet core criteria, and the need for appropriate action in legislation.
- Release of subsequent CMS guidance to manufacturers on price reporting requirements that pertain to value-based contracts. CMS should provide continuing, timely guidance to manufacturers.^b

3. The Office of the Inspector General in the U.S. Department of Health and Human Services: Create appropriate safe harbor protection under the Anti-Kickback Statute in three areas

Guidance outlining appropriate safe harbor protection under the Anti-Kickback Statute should be promulgated to allow manufacturers to engage in three priority areas in support of value-based contracts: data and analytics, warranties of performance, and medication adherence support services and interventions.

Three aspects of valuable-based contracting warrant appropriate safe harbor protection under the Anti-Kickback Statute. The Office of the Inspector General of the U.S. Department of Health and Human Services has jurisdiction over such safe harbors, but appropriate congressional action could be taken as well. Once again, new safe harbor protections should be in conformance with a broader vision and set of goals for value-based contracting such as that outlined above. The following are the three priority areas for new protections.

b. Timely guidance should extend as well to contracts for pharmaceuticals that are subject to Medicare's Average Manufacturer Price (AMP) calculation, which applies to products that are not typically dispensed by community pharmacies, including some products that are administered by infusion, injection, instillation, implantation, or are inhaled (so-called "5i" drugs).

Data and analytics

Data collection and analysis to confirm achievement of agreed-upon goals or outcome measures are central to value-based contracting. Manufacturers and payers may elect to share costs of data collection and analysis or allocate them to the manufacturer. As noted above, currently, a manufacturer's assumption of these costs might be considered an unlawful inducement under the Anti-Kickback Statute. New safe harbor protection could stipulate that payers and manufacturers demonstrate clearly, and document the reasons that, the costs of data collection and analysis are to be allocated as proposed in their contract.

Warranties of performance

Warranties are one of 26 types of transactions afforded some measure of protection from enforcement of the Anti-Kickback Statute.^c Warranties are generally defined as a promise by a manufacturer or supplier to replace, refund, or reduce the price of a health care product if the product proves to be flawed or defective upon delivery, or does not perform to an agreed-upon standard. Warranties for pharmaceuticals can be defined as a guarantee by the manufacturer to replace a shipment of drugs if they prove defective. Safe harbor protection may also encompass a guarantee that the manufacturer will compensate a purchaser if a drug, as actually used among patients, does not prove as effective as advertised. But manufacturers contend that the existing safe harbor was not drawn up specifically to provide a warranty on how patients respond to use of a drug, or in the context of value-based contracts in general. An updated safe harbor protection under the Anti-Kickback would explicitly allow for scenarios in which a manufacturer promises to refund the cost of therapy for cases in which an individual patient, or a specifically-defined patient population, does not respond to treatment or does not benefit according to an agreed-upon level of effectiveness.

Medication adherence support services and interventions

Under many forms of value-based contracting, both manufacturers and payers have a heightened interest in promoting and monitoring patients' adherence to medications. Poor or sub-optimal patient adherence undermines the purpose of the contract, and can lead to the appearance that the drug may be ineffective for clinical reasons, rather than because the patient did not use the drug as prescribed.

Value-based contracts should specify the exact adherence services or supports that manufacturers provide under a contract, and the services and supports should be provided in a way that is clearly not linked to the volume of drugs dispensed to patients. In other words, adherence services should not be used as inducements to prescribe the drug in question. Agreements that meet these specifications should be safe harbored under the Anti-Kickback Statute.

4. *The U.S. Food and Drug Administration*: Finalize new guidance on manufacturers' communication with payers

FDA should finalize guidance on the exchange of health care economic information.

More broadly, FDA should engage stakeholders in discussion about current restrictions on communication about off-label uses, as these communications relate.

c. The 26 categories of safe harbor protection under the Anti Kickback Statute are defined at 42 CFR 1001.952

As detailed above, FDA is likely to provide final guidance in 2017 on three issues that could help catalyze value-based contracting for pharmaceuticals: exchange of health care economic information from manufacturers to payers and to other entities that are at financial risk for coverage and reimbursement of pharmaceuticals; authority for manufacturers to convey such information to payers before a drug is approved; and authority for manufacturers to pro-actively provide health care economic information to payers. Final guidance in these areas is thus likely to support value-based contracting, but is not likely to include guidance with respect to manufacturers' communication with payers about unapproved, off-label uses of pharmaceuticals.

The question for payers and manufacturers is whether the current restrictions on communication about off-label uses actively impede value-based contracting, particularly for cancer drugs that are frequently used off label as clinicians seek the optimal treatment for patients. NEHI recommends that stakeholders re-engage on this question in the future, as there may be opportunities to craft careful, safeguarded protections for off-label communication between manufacturers and payers.

IV. CONCLUSION

As this white paper has spelled out, on balance, NEHI's stakeholder group largely believes that value-based contracting is an innovation that should move forward. There are few if any alternatives to pharmaceutical pricing issues that are as market-based as these arrangements, or that have as much support among different sectors (e.g., manufacturers, payers, and government). As noted, value-based contracting is in keeping with the general movement to more value-based payment within health care, and it is possible that many alternative payment models will simply not be sustainable unless pharmaceuticals are included.

Given the almost certain influx of many innovative, high-cost drugs into the market in coming years, value-based contracts may afford the best available opportunity for managed entry into the health system of these new products. The lessons learned in executing these contracts may help also help to inform future biopharmaceuticals research, development, and innovation.

As noted, many challenges exist to value-based contracting for biopharmaceuticals, and multiple changes in policy and operations will be needed if these approaches are to become more widespread. None of these changes will occur overnight; some will be best tested through pilots and demonstrations that can be evaluated and modified over time. There will be ongoing need for monitoring, research, and thoughtful leadership across cross-sector groups similar to the one NEHI brought together for this effort.

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Authors:

Thomas E. Hubbard, Vice President of Policy Research, NEHI
Susan Dentzer, President and CEO

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About NEHI:

NEHI is a nonprofit, non-partisan health policy institute focused on enabling innovations that improve health, boost health care quality, and lead to more sustainable health spending.

In partnership with its member organizations from across the health care ecosystem, NEHI conducts and fosters independent, evidence-based research to move ideas into action. Our broad membership both informs and uses our research, producing insights and policy consensus with unique credibility. NEHI brings an objective, collaborative, and fresh voice to formulating health policy.

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One Broadway, Cambridge, MA 02142 | 617.225.0857 | www.nehi.net