REWARDING RESULTS

Moving Forward on Value-Based Contracting for Biopharmaceuticals

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 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 commmunication 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.

THE STATUS QUO

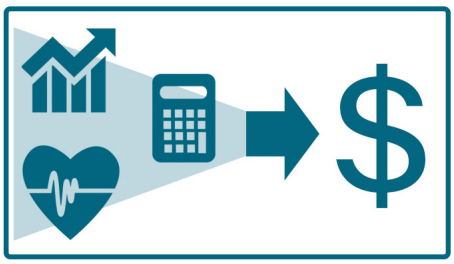
Payers and Manufacturers Negotiate Discounts and Rebates – Regardless of How Drugs Are Used and Results They Achieve

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)

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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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