VALUE-BASED CONTRACTING FOR PRESCRIPTION DRUGS AND MEDICAL DEVICES: AN INNOVATIVE SOLUTION IMPAIRED BY OUTDATED REGULATIONS

Barry H. Boise, Esq.
Barak A. Bassman, Esq.
Mary Margaret Spence, Esq.
Hilary LaBar, Esq.
Pepper Hamilton LLP
Philadelphia, PA

Introduction

Often lost in the cacophony of headlines surrounding rising healthcare costs is the promise that value-based contracting offers as a possible solution. In contrast to the traditional fee-for-service model, value-based contracting conditions the price of medical goods and services on demonstration of delivered benefit to patients. In recent years, value-based contracting has gained significant traction in the hospital and physician setting, and it is beginning to make inroads into the prescription drug and device setting. Advances in technology and big data – a term describing the large volume of data sets produced each day that may be analyzed to reveal patterns, trends and associations – increasingly allow for aligning payment to evidence of health outcomes. Payors, government and industry have all endorsed the concept of applying value-based contracting to prescription drugs and devices.

Significant regulatory obstacles, however, stand in the way of fully recognizing the potential for value-based contracting in the prescription drug and device arena. The current federal regulatory scheme for medicines and devices, which was designed around traditional fee-for-services models, is ill-suited to value-based models. This article discusses the potential impediments to value-based contracting for medicines and devices posed by the Medicaid “best price” rule, the Anti-Kickback Statute (“AKS”) and regulations governing off-label promotion. The services that a drug or device manufacturer may wish to offer in connection with a value-based contract raise AKS concerns that may not be present in value-based contracting for physician and hospital services, and Medicaid regulations on the best price for prescription drugs and Food and Drug Administration (“FDA”) regulations on off-label promotion make value-based contracting in the drug and device arena particularly challenging. The complex way in which drugs, in particular, are distributed and reimbursed also raises challenges not continued on page 3
present for other producers of healthcare.

This article also discusses certain contractual considerations for parties contemplating value-based contracting for medicines and devices.

The Trend Towards Value-Based Contracting

Value-based contracting is an important trend in the healthcare field. Federal and state governments endorse the premise of value-based contracting in certain portions of the healthcare ecosystem. For example, the Medicare Access and CHIP Reauthorization Act of 2015 promotes alternative payment models for compensation of physicians, and, under the Obama administration, the Centers for Medicare & Medicaid Services (“CMS”) announced a goal of tying 50 percent of Medicare fee-for-service payments to some value-based measure by the end of 2018. The commercial health insurance industry is excited about the transformative potential of value-based reimbursement. Marilyn Tavenner, president of America’s Health Insurance Plans, a leading trade group of commercial payers, has written that “[w]e’re continuing to move away from the outdated fee-for-service model that prioritizes volume and transactions. Instead, health plans are working to refocus the delivery system on rewarding quality outcomes rather than how many tests and procedures take place.”

In the prescription drug and device space, the availability of big data increasingly allows for collecting information about the value that prescription drugs and devices provide, on both a patient and population level. For example, patient data can help predict who is most likely to respond to a medication, and at what level of dosing, or who is most likely to suffer a side effect. Wearable devices and other digital health applications permit the collection of data on adherence, efficacy and safety. Data collection is imperfect at this juncture, but is rapidly evolving. As electronic health records become more prevalent and standardized, the healthcare industry will have access to a wealth of information that allows for more precise evaluation of outcomes related to the use of prescription drugs and devices. Increasingly, payors for medicines and medical devices are looking for ways to use these data to connect the price of products to their value to patient health.

In 2016, for example, Novartis entered into highly publicized value-based contracts with insurance giants Cigna and Aetna for its heart failure medication Entresto. The contracts tie the price of the medication to reduced heart failure hospitalizations. Novartis Chief Executive Officer (“CEO”) Joseph Jimenez has stated that he believes that the pharmaceutical industry “must shift to a model that focuses on value and outcomes delivered.” As he explained, “[w]e believe in the efficacy of our products, and by collaborating with payers on solutions for reimbursement, we hope to help start a shift toward value pricing in the healthcare system. We want to be rewarded for the tangible outcomes our products provide patients, not for simply selling pills.”

Published reports show that value-based contracting has also been applied to the diabetes medications Januvia and Trulicity and to the cholesterol medications Repatha and Praluent, as well as other medications. The Center for Evidence-based Policy at the Oregon Health & Science University is leading an initiative to explore value-based contracting for medications for state Medicaid organizations. Medical device manufacturers are also moving towards a value-based model, pairing data analytics and other services with their products to maximize value to patients and providers.

Regulatory Obstacles to Value-Based Contracting

Existing federal laws and regulations, however, could stymie widespread adoption of value-based contracting in the prescription drug and device setting. For example, the Medicaid “best price” rule, the AKS and regulations governing off-label promotion all provide potential liability pitfalls for a manufacturer that wishes to engage in value-based contracting.

The Medicaid “Best Price” Rule

In order for prescription drugs to receive coverage through the Medicaid program, manufacturers are required to enter into rebate contracts with CMS. The Medicaid “best price” rule, which was first enacted in 1990, requires that CMS receive the lowest price for a medication that the manufacturer offers to any other payor in a set time period, inclusive of any applicable discounts and rebates. Under the value-based contracting model, the ultimate price for a medicine will not be determined upfront, but will depend on rebates or other adjustments for price based on health outcomes data. For a manufacturer that engages in value-based contracting with other payors, a number of questions arise. Are Medicaid agencies (federal and state) also entitled to any value-based rebate that a private payor receives, even if they and the payor serve different patient populations where the value of a medication may differ? How does a manufacturer calculate the best price in the statutory time period, given that the ultimate price that a private payor pays under a value-based contract will not be known until data are collected? As price is tied to outcomes in commercial contracts, is the Medicaid program entitled to assume that the

continued on page 4
Value-Based Contracting for Prescription Drugs and Medical Devices

continued from page 3

medication will perform poorly so that it can take advantage of the theoretically lowest price under the value-based arrangement?

When the best price rule was revised in April 2016, CMS recognized in its comments that value-based contracting for pharmaceutical products could provide benefits to patients and that further guidance on how to treat these arrangements for purposes of the best price rule was needed:

With the recent introduction of value-based purchasing arrangements in the pharmaceutical marketplace, we recognize the value of such arrangements especially when they benefit patients. We are also interested in assuring that states and Medicaid programs have clarity as to how these arrangements might exist in Medicaid. Therefore, since these arrangements are unique, we are considering how to provide more specific guidance on this matter, including how such arrangements affect a manufacturer’s best price.

Despite the promise by CMS in April 2016 that it was “considering how to provide more specific guidance,” CMS has been silent on this important topic. The only hint that CMS is alert to the issues is a July 2016 notice that recommends that manufacturers “consult both the statute and implementing regulations regarding the determination of best price.” CMS has promised to issue more specific guidance in the future, but, until it does so, the best price rule as it exists in its current form (coupled with the lack of guidance surrounding it) will deter value-based contracting.

A white paper co-authored by Eli Lilly and Anthem offers possible regulatory solutions, including updating the best price statute and regulations “to exclude from best price certain rebates and other price concessions paid from manufacturers to health plans that are the result of value-based contracting (e.g., additional rebates paid if a patient does not respond to treatment) . . . .” CMS could also be authorized to create pilot programs to test how value-based contracts and alternative approaches to Best Price impact reported government price figures, and in turn, Medicaid rebate amounts . . . .” To date, however, no such reforms have been implemented.

The Anti-Kickback Statute

The AKS generally prohibits the exchange (or offer to exchange) of anything of value to induce or reward the referral of federal healthcare program business. While there are several regulatory safe harbors that protect certain business and payment practices from AKS prosecution, services offered by a manufacturer in connection with a value-based contract may not neatly fit within any current regulatory safe harbor. In December 2016, the Department of Health and Human Services’ Office of Inspector General (“OIG”) issued its annual solicitation for proposed changes to the AKS regulations, which recognized the limitations of the current safe harbors to accommodate certain contractual arrangements that could violate the AKS but nonetheless be beneficial. Multiple pharmaceutical and device companies responded, identifying specific situations that the regulations should be amended to cover in order to promote value-based contracting. The responses reflect a growing movement within the industry to explore value-based contracting arrangements.

For example, AdvaMed, a trade association representing manufacturers of medical devices, diagnostic products and health information systems, raised the concern that offering purchasers of devices free ancillary services, such as data analytics or follow-up lab testing, could be viewed as an illegal kickback. AdvaMed also expressed concern that the AKS would prevent a medical technology company from providing a hospital with a bundle of services designed to achieve a specific clinical outcome and from paying a rebate if the outcome was not achieved. For example, it may make perfect clinical and logical sense to bundle services such as technology, consulting, training and patient monitoring that cover the different ways in which a device company may contract with a hospital. Discounts in connection with a bundled sale, however, do not qualify under existing safe harbors. This is because there is only safe harbor protection for services, which are “reimbursed by the same Federal health care program using the same methodology,” which could exclude the type of value-based service bundle that a manufacturer wishes to offer in the example.

PhRMA, which represents pharmaceutical manufacturers, also identified limitations to the existing AKS safe harbors, including inadequate protections for companies that want to provide personal services to buyers in addition to medications. Under current regulations, for example, an agency agreement that provides services on a periodic or part-time basis must specify “exactly the schedule of such intervals, their precise length, and the exact charge for such intervals.” But the personal services that a manufacturer could provide in connection with a value-based contract are subject to variability and may evolve over the course of a contract. For instance, the services may need to be tailored in order to meet needs of the purchaser that will only become apparent over the course of performance of the contract.

Similar concerns about current limitations on providing ancillary
services and bundled services were voiced by manufacturers Medtronic and Lilly. For example, data analytics could be offered to payors or other purchasers as part of ancillary or bundled services. Data analytics play a vital role in understanding and interpreting real-world patient events and outcomes, but manufacturer-provided data or analyses, such as medication adherence programs, could constitute improper remuneration because they do not fit neatly within any existing AKS safe harbor when tied to the ultimate price of the drug. Some have advocated for an amended “adherence safe harbor” that would focus on the role of manufacturer-provided adherence programs in the context of value-based pricing arrangements (e.g., tracking specific dosage, time on the medication, refills, etc.).

Industry has also advocated modifying the existing warranties safe harbor, which limits any warranty to the cost of the item itself. The existing safe harbor would not cover, for example, payment for corrective services if the targeted clinical outcome under a value-based contract is not achieved. Nor does the existing safe harbor allow manufacturers flexibility in determining the types of warranties that could be offered for products that do not work as specified (e.g., reimbursement of copayments or new products in exchange for damaged or defective products). A revised warranty safe harbor would facilitate issuing refunds when products do not meet defined requirements for individual patients or patient populations.

The industry responses also suggested safeguards to accompany their proposed amendments that would appropriately protect against the types of abuses that the AKS is intended to prohibit. For example, both Lilly and Medtronic suggested including language to ensure that value-based pricing arrangements do not affect clinical decision-making; steer patients to higher-cost medicines, providers or practitioners; or encourage over-utilization of medications, referrals or services. Similarly, Medtronic suggested that safe harbors created for value-based pricing should contain a transparency requirement that would ensure that a manufacturer discloses value-based pricing arrangements to different providers, payors (including the government) and patients.

The responses to the OIG’s request for proposals highlight the limitations of the current AKS regulatory regime in allowing for value-based contracting. In order to promote value to patients and cost savings, the OIG should work toward implementing regulations that allow for more flexible value-based contracting arrangements. The OIG has not yet commented on any of the proposals recently submitted by industry.

Off-Label Communications

FDA takes the position that a manufacturer is precluded from promoting off-label uses of its products with any member of the public, including physicians, patients and payors. This position, the subject of extensive legal challenge, may be another potential impediment to effective contracting.

For example, an antidepressant may not only treat depression. It also could lead to patients taking better care of other aspects of their physical health, which could in turn result in cost savings for payors. A payor also may want to cover use of a medicine that is entirely off-label if that use benefits patients, even in the absence of data required by FDA in order to obtain an indication. Or a payor could choose to pay only for on-label uses of a medicine, or pay different prices for on-label and off-label uses of the medicine. A payor could even price different on-label uses differently.

In order to make these decisions and to set the price for a prescription drug under a value-based contract, a payor will require access to information about all uses of a medication, including off-label ones. A payor could also seek other data that are not strictly on-label, such as data on dosages or use durations not described on the label. If the price for a medication is to be an accurate reflection of the value that it provides, manufacturers need to be able to supply complete, accurate, truthful and nonmisleading health outcome data without fear of running afoul of the prohibition on off-label promotion.

In January 2017, FDA issued draft guidance regarding communication to payors, formulary committees and similar entities of healthcare economic information (“HCEI”) that is “related to” an approved indication. The guidance recognizes a public health need for manufacturers to provide to payors information about their medications that is not strictly within the four corners of the label, and partially addresses the obstacles that the prohibition on off-label promotion poses for value-based contracting. However, it is not a binding statement of FDA policy, and it does not address all types of communications that may be necessary for value-based contracting to thrive.

The guidance states that FDA does not consider HCEI that “directly relates to an approved indication” to be false or misleading when accompanied by a “conspicuous and prominent statement describing any material differences” between the HCEI and the approved labeling. The guidance makes clear that any communications must be based on “competent and reliable scientific evidence” and should note any limitations to the data.

In order to be considered “related to” an approved indication, HCEI “should relate to the disease or condition, manifestation of the disease or condition, or symptoms associated with the disease or condition in the patient population for which the medicine is indicated in the FDA-approved labeling.” FDA provided several examples of information that would meet this test, including:

continued on page 6
Value-Based Contracting for Prescription Drugs and Medical Devices

continued from page 5

- Information about the long-term use of the medicine for the approved indication over a period that is different from that addressed in the studies described in the FDA-approved labeling;
- HCEI analyses based on studies of broad management of a disease for which the medicine is indicated, including economic consequences of treatment on clinical outcomes (e.g., economic consequences of absent work days as a result of signs and symptoms associated with a disease);
- HCEI analyses based on clinical data demonstrating an effect on a surrogate endpoint that is known to predict clinical benefit (i.e., a validated surrogate endpoint) (e.g., lipids and cardiovascular outcomes); and
- HCEI analyses based on studies comparing the safety or effectiveness of a medicine for its approved indication to another medicine or intervention or to no treatment.

In contrast, FDA would not consider the following types of HCEI analyses to be related to the product indication:

- An economic analysis of disease course modification related to use of a medicine that is approved only to treat the symptoms of the disease (e.g., an analysis of a medicine indicated for the acute relief of angina discussing the effect of the medicine on delaying the worsening of coronary artery disease)
- HCEI analyses derived from studies in patient populations that are not within the indicated patient population.

The draft guidance also recognizes the need for manufacturers to communicate certain information about investigational products, which “may help payors plan and budget for future coverage and/or reimbursement decisions prior to FDA approval or clearance of investigational products.”

The draft guidance represents a step in the right direction in terms of manufacturers’ ability to engage in value-based contracting. FDA has recognized a need for manufacturers to communicate information about their products outside of the label, particularly to payors. FDA has also identified specific examples of information that manufacturers can communicate that will be helpful in assessing value and pricing medications accordingly.

However, the guidance is far from comprehensive, and there is a significant gray area as to when FDA might consider an enforcement action based on a manufacturer’s communications to a payor. Whether FDA will deem a communication false and misleading is a fact-specific inquiry, and a communication that does not fall neatly within any of the examples FDA provides will give a manufacturer pause before providing information to a payor. For example, could a manufacturer share HCEI analyses based on clinical data demonstrating an effect on a surrogate endpoint that is thought to provide a clinical benefit, but has not yet been “validated” in the eyes of FDA? If a manufacturer is providing a comparison of its medication to another drug, does the other drug need to be approved for the same indication? Furthermore, the guidance does not afford reassurance to a manufacturer that wishes to provide information about its medications unrelated to an approved use, even if this information would be relevant to how a payor determines value, such as the impact of a behavioral health medication on physical health outcomes. FDA closed public comment on the draft guidance on April 19, 2017, but has not yet given any indication as to when it may finalize the guidance.

Value-Based Contracting – Additional Contractual Considerations

In addition to regulatory constraints, a manufacturer must also consider additional hurdles to value-based contracting. In negotiating any value-based contract, the first step that the contracting parties must take is to clearly define the health outcome on which price will be contingent and how that outcome will be assessed. For some products, the metric can be a straightforward measure, such as lab values or repeat hospitalizations; for others, setting the criterion or criteria may be more complex. The outcome metric should not only be objective, but should also be an accurate proxy for the economic value of a prescription drug or device. In other words, for the contractual arrangement to be attractive to the payor or other purchaser, the outcome should readily translate to cost savings. Without careful attention to objective endpoints, disputes will arise as to whether value has actually been conferred.

The parties also will need to take into account challenges in collecting the relevant data. For example, accurate collection of data could depend on patients’ utilizing wearable devices or software applications. Payor databases, though useful, are limited because patients change insurers, drop insurance altogether, or pay for services by cash, especially out of network. Different providers can also vary in the intensity and accuracy of their coding for patients’ medical conditions, further confounding the data. Patient noncompliance with medication also impacts the ability to accurately assess the value of the medication, particularly in low-income risk pools like the Medicaid population, where finances, transportation and other barriers affect adherence to patient care. Integration of data from different systems or data
sources may also be necessary. Standardization of data that can be used across sources, such as through universal electronic health records, would help address data collection issues.

The CEOs of Novartis and Roche have recognized that improvements in data collection are needed for value-based contracting to become widespread.34 As Novartis CEO Jimenez stated, “The basic infrastructure of electronic medical records, let’s call it ‘real-world data,’ is going to have to increase so that we can easily track and monitor outcomes.”35

The Network for Excellence in Health Innovation, a nonprofit organization dedicated to identifying innovations that improve the quality and lower the costs of healthcare, has similarly recognized that “operationalizing value-based contracts still requires investment, especially in data collection and analysis.”36

Timing of contracts is also an important consideration. For instance, the window for fully realizing the value of a medication may be longer than a patient’s typical one-year enrollment period in an insurance plan. For example, a cardiovascular medication could prevent hospitalizations years down the line. However, when patients drop out of a plan or change insurance coverage, the payor may not realize the value of the medication as to these patients. A value-based contract with a payor will therefore need to take into account the ebb and flow of patients in and out of insurance plans. Some states are experimenting with developing statewide databases of all payors,37 which will help to address this issue, although the databases will still be limited as patients move across state lines, switch into coverage that may be outside a state’s data collection scope (e.g., Medicare), or drop coverage altogether. In addition, companies like IMS Health have anonymized patient longitudinal data (“APLD”) products that attempt to match patients (in a de-identified way) over time through various medical records.38

Conclusion

Value-based contracting is an exciting and emerging approach to ensure that the prices charged for prescription drugs and medical devices reflect their real-world value to patients. But certain hurdles stand in the way, including a regulatory scheme that was not designed with value-based contracting in mind.

There are signs of progress. The OIG now has before it concrete proposals for new safe harbors to the AKS that would facilitate value-based contracting. CMS has recognized that some adjustments in the best price regulations may be necessary to account for the existence of value-based contracting, although it has yet to propose any concrete solutions. Similarly, recent FDA draft guidance recognizes that manufacturers will need to communicate some information outside of the label to payors.

But much more work remains on the regulatory front in order to create an environment where value-based contracting for medicines and devices can flourish. Manufacturers and payors should work with legislators and regulators to modify existing laws and regulations to accommodate value-based contracting for prescription drugs and devices.

The authors are members of Pepper Hamilton LLP’s Health Sciences Department, a team of 110 attorneys who collaborate across disciplines to solve complex legal challenges confronting clients throughout the health sciences spectrum.

Barak A. Bassman, partner, concentrates his practice on healthcare and antitrust litigation and counseling. He has extensive experience in representing healthcare providers, third-party payors and life sciences companies in payment disputes, antitrust issues, managed care contract negotiation and termination and regulatory challenges. He has also represented many clients outside of healthcare in antitrust litigation and counseling. He may be reached at bassmab@pepperlaw.com.

Barry H. Boise, partner and member of the Health Sciences Department Leadership Team, defends and counsels pharmaceutical, medical device and life sciences companies. His primary emphasis is the counseling and defense of pharmaceutical and medical device companies from early stage through marketed products. He has substantial experience litigating multidistrict litigation and coordinated state court litigation. Mr. Boise represents life science and healthcare companies in attorney general investigations and litigation, and in other civil and criminal actions involving healthcare fraud and abuse. He may be reached at boiseb@pepperlaw.com.

Barry H. Boise, partner and member of the Health Sciences Department Leadership Team, defends and counsels pharmaceutical, medical device and life sciences companies. His primary emphasis is the counseling and defense of pharmaceutical and medical device companies from early stage through marketed products. He has substantial experience litigating multidistrict litigation and coordinated state court litigation. Mr. Boise represents life science and healthcare companies in attorney general investigations and litigation, and in other civil and criminal actions involving healthcare fraud and abuse. He may be reached at boiseb@pepperlaw.com.

Mary Margaret Spence, senior attorney, focuses her practice on the defense of products liability and consumer fraud cases involving prescription drugs and medical devices. Ms. Spence also has experience providing regulatory counseling to life science companies. She may be reached at spencemm@pepperlaw.com.

Hilary E. LaBar, associate, focuses her practice on the defense of pharmaceutical and medical device manufacturers in products liability litigation in federal multidistrict and state coordinated proceedings. Ms. LaBar also provides regulatory and risk management counseling for pharmaceutical and medical device manufacturers on compliance with FDA promotional requirements, state and federal laws and regulations, and

continued on page 8
risk mitigation related to product labeling and promotional claims. She may be reached at labarh@pepperlaw.com.

Endnotes

1 In the prescription drug context, a value-based contract will likely be between the manufacturer and a pharmacy benefit manager, insurance company or other payor that negotiates rebates with a manufacturer for the cost of prescription drugs. Although wholesalers, pharmacies and hospitals are the direct purchasers of drugs, the payor bears the primary burden of payment and decides which medications will be covered for their beneficiaries. In the device setting, a value-based contract can be between the manufacturer and a hospital or health system, which is often the primary decision-maker on which devices it will use in its facilities.

2 See 42 U.S.C. § 1395l(t).

3 See https://www.cms.gov/Newsroom/MediaReleaseDatabase/FactSheets/2016-03-03-2.html. Please note that Dr. Thomas E. Price, the Secretary of Health and Human Services for the Trump administration, has voiced his opposition to the primary decision-maker on which devices it will use in its facilities.

4 See https://www.ahip.org/value-whats-right-for-patients.

5 See, e.g., Daniel Richard Leff & Guang-Zhong Yang, Big Data for Precision Medicine, Engineering 2015, 1(3): 277-279; University of California - San Diego, Researchers are on their way to predicting what side effects you'll experience from a drug, ScienceDaily (Nov. 2015); Denise Myshko & Robin Robinson, Personalized Medicine: From Bench To Bedside, PharmaVOICE (June 2014).


8 Id.


13 42 C.F.R. § 447.505(a).


16 Id.


18 42 U.S.C. § 1320a-7b.


21 42 C.F.R. § 1001.952(h)(5)(ii). The OIG has stated, for example, that items reimbursed under a Diagnosis Related Group ("DRG") payment for hospital inpatient services would qualify as items reimbursed under the “same methodology.” See 64 Fed. Reg. at 63,330.


23 42 C.F.R. § 1001.952(d)(3).


25 42 C.F.R. § 1001.952(g)(4).


29 FDA Payor Guidance at 5.

30 Id.

31 Id.

32 Id. at 15.


35 Id.

