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The Honorable Charles E. Grassley
U.S. Senator
Committee on Finance
209 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Ron Wyden
U.S. Senator
Committee on Finance
209 Dirksen Senate Office Building
Washington, DC 20510

Dear Senators Grassley and Wyden:

As one of the nation's leading health plans, Anthem, Inc. appreciates the Senate Finance Committee's continued focus on the issue of rising drug prices and the resulting impact on private and public healthcare coverage. We continue to recognize the vital role prescription drugs play in medical treatment today. However, we contend that improving transparency and driving towards a pricing system more focused on value, are necessary steps towards mitigating cost growth and improving affordability. In responding to the questions posed by the Committee, we ask that Congress consider steps that would improve transparency earlier in the FDA process and provide better insight into the expected price of prescription drugs, while also mitigating challenges that inhibit the transition towards a value-based system that takes into consideration the careful balance of clinical quality and affordability.

What are the effects of a breakthrough, single source innovator drug on the marketplace?

The Breakthrough Therapy Designation (BTD) program began in July 2012 and has changed the manner in which certain drugs are developed and approved in the U.S. The BTD pathway affords drugs that treat serious or life-threatening conditions expedited drug development and review by FDA. To receive a BTD, the drug sponsor must show with clinical evidence that, compared to other available therapies, its drug may substantially improve at least one clinically-significant endpoint. This relatively new process increases the speed at which certain specialty drugs can reach the market in the U.S., creating sudden, unexpected new costs for the entire health care system.

The BTD program also poses significant challenges for payers which must develop criteria governing insurance coverage for such drugs based on more limited clinical evidence than might otherwise be available if the drugs were not approved on an expedited basis. Breakthrough drugs in particular reflect evolving recommendations for use and treatment (in some cases after the drug has been approved) and, as such, the BTD process should not be viewed as a litmus test for coverage determinations in all circumstances. Since BTD drugs can be approved on a faster track (with pricing and labeling not published until the drug is ready for marketing), all stakeholders, including state Medicaid agencies, employers, and health plans are limited in their ability to anticipate costs associated with these new high-priced drugs. Though the pricing issue became most evident when the Hepatitis C drugs, Sovaldi® and Harvoni, came to market, this trend has only continued as additional breakthrough drugs have been brought to market. We would also note that while the continued issue of cost has been succinctly examined in this report, another unforeseen result of expedited pathways such as breakthrough designation that serve to bring needed treatments to patients more quickly, is the impact of drugs being approved with more limited clinical evidence. For this reason we recommend, in the responses that follow below, that manufacturers release this clinical evidence and other information to assist stakeholders in anticipating cost increases and crafting appropriate criteria for coverage of breakthrough drugs.

Do the payers in the programs have adequate information to know the cost, patient volume, and increases in efficacy of a new treatment regimen?

In the current environment, one of the top challenges payers face is that we simply lack the necessary information to accurately estimate the price of new treatment regimens, which includes a lack of information about the unit price and the label that indicates the target population. In addition, health plan Pharmacy and Therapeutic (P&T) Committees do not have all the information about new treatments to take into account key clinical safety concerns. Additionally, with respect to existing drugs, prices can change without warning, which can create similar challenges.

The current situation where there is a lack of information about price and clinical utilization is particularly challenging in the post-ACA environment, where health plans, employers, and governments at every level are establishing premium rates and/or budgeting for coverage often 18-20 months in advance. This situation is a challenge across virtually all lines of health benefits, including individual market, small employer market, large employer market, Medicaid, and Medicare. Not only are premium rates and budgets set far in advance, but stakeholders have little ability to adjust them mid-year to reflect changes in drug costs.

We strongly support injecting more transparency in pharmaceutical drug pricing needed for health plans, employers, and governments in order to mitigate the uncertainty that can lead to unexpected cost increases on consumers. The corresponding table on question 4 further outlines our position in support of pricing, labeling and research transparency.

What role does the concept of "value" play in this debate, and how should an innovative therapy's value be represented in its price?

Anthem supports legal and regulatory changes to create a policy environment conducive to allowing health plans and manufacturers to enter into a variety of value-based contracting arrangements, aligned with the shift toward value-based payment and the goal of promoting access to high-value care. Anthem partnered with the biopharmaceutical manufacturer Eli Lilly to release policy proposals that would help mitigate the barriers to value based contracting for drugs. We have attached the op-ed that announced that work along with the two policy papers that outline needed changes.

The first policy area that needs to be improved is addressing the current regulations that have a chilling effect on manufacturers having appropriate discussions with insurers prior to FDA approval. Because such conversations could be construed as illegal marketing, conversations are less robust than they would be otherwise. Thus, we are looking for legal changes that would make it clear that health plans and manufacturers can have appropriate discussions about pre-approval drug clinical data, including the product's efficacy, safety, and pharmacoeconomic information prior to FDA approval.

The second policy area is related to existing rules that have the unintended consequences of making it more difficult to enter into value-based agreements. Our paper calls for changes to exempt value-based agreements from Medicaid best-price reporting and the creation of a safe-harbor in anti-kickback statutes.

Anthem acknowledges that it will be important to allow for the emergence of value-based arrangements as part of the broader health system transformation and assure continued efficiency for government programs and patient access.

What measures might improve price transparency for new higher-cost therapies while maintaining incentives for manufacturers to invest in new drug development?

As stated above, the current process where (1) drug prices and labels for new drugs aren't available until the day the drug is approved for sale and (2) price changes for existing drugs can change mid-year without warning, is completely incompatible with the fact that health plans set rates for most lines of business 18-20 months in advance. This situation results in significant uncertainty that can wreak havoc on budgets for health plans, employers, and governments at every level, and result in higher premiums for consumers. Anthem would thus support the following proposals related to transparency:

| Needed Transparency Solution | Details of the Proposed Policy Change |
|--|--|
| Pricing transparency | Establish the following manufacturer transparency proposals: <ul style="list-style-type: none">• For new drugs: When drug is filed for FDA approval, manufacturer must publish the unit price (median review time: 12 months).• For existing drugs: Publish anticipated increases in drug prices 12 month in advance, to allow ample time for payers to understand the financial impact these increases will have on existing member benefits and premiums. |
| Labeling transparency | FDA must publish all iterations of the label being discussed with the manufacturer during the review process. |
| In-house clinical data for “breakthrough” drugs | As part of any submission for FDA approval with “breakthrough” designation, drug manufacturers must release all relevant clinical data, including complication reports and outcome data, and continue to release that data on an ongoing basis, within four weeks of milestones being completed. |
| Determining the drug’s “Value Proposition” | In addition to publishing the maximum price at the time of the FDA filing, the manufacturer must also publish the value proposition of the drug that is tied to that expected maximum price. That value proposition analysis shall include: <ul style="list-style-type: none">• Cost impact to the healthcare system• Comparative value relative to existing drugs |

What tools exist, or should exist, to address the impact of high cost drugs and corresponding access restrictions, particularly on low-income populations and state Medicaid programs?

We recommend adopting the policy changes noted above to help remove uncertainty from the system. Since BTM drugs can be approved on a faster track (with pricing and labeling not published until the drug is ready for marketing), state Medicaid agencies and health plans are limited in their ability to anticipate

prices associated with new high-priced drugs. Specifically, states may not have priced correctly for a plan year in which a high-priced/high-utilization drug quickly comes to market. Experience with BTB drugs such as the new Hepatitis C drugs demonstrates the importance of Medicaid state agencies having sufficient information to forecast the price of such drugs before they enter the market. For these reasons, we recommend adopting the policy changes noted above to help remove uncertainty from the system.

Again, we thank the Committee for its continued focus on the need to address high-priced pharmaceutical drugs, and for the opportunity for Anthem to provide input. We stand ready to further assist the Committee in the weeks and months ahead. Please direct any follow up questions or concerns to Sam Marchio, Regional Vice President of Federal Affairs, at 202-628-7831 or via email at Samuel.Marchio@Anthem.com.

Sincerely,

A handwritten signature in dark ink, appearing to read 'Elizabeth P. Hall', with a stylized flourish at the end.

Elizabeth P. Hall
Vice President, Federal Affairs

About Anthem, Inc.

Anthem is working to transform health care with trusted and caring solutions. Our health plan companies deliver quality products and services that give their members access to the care they need. With over 72 million people served by its affiliated companies, including more than 38 million enrolled in its family of health plans, Anthem is one of the nation's leading health benefits companies. For more information about Anthem's family of companies, please visit www.antheminc.com/companies.

Discovering New Medicines And New Ways To Pay For Them

By Samuel Nussbaum, MD and David Ricks

While the rest of the healthcare system is moving toward paying for value, payments for drugs largely continue to be stuck in a 20th century construct that focuses on price, regardless of the health outcomes of each patient. This lack of payment innovation is particularly damaging in an era where on the horizon new treatments and cures promise great benefit for consumers, but also bring great upfront costs for individuals, employers and governments at every level. We must find a new path forward.

Paying for value requires evaluating new treatments in the context of total health costs for the patient. For example, value could be measured according to improvement in outcomes over a previous standard of care -- pharmaceutical, surgical or otherwise. Or value could recognize that certain individuals may experience better results than others. We know from experience that value-based payments are multidimensional and evolve with experience.

While there are no silver bullets, we believe it is possible to start breaking down some of the hurdles that stand in the way of a value-oriented system. Anthem and Lilly are working together to help drive policy changes that will facilitate the transition.

As a health benefits company and a biopharmaceutical company, we approach this problem from different perspectives but with common ground. We cherish the value of medical innovation – both in discovery and delivery. We believe that innovative medicines can be an incredibly powerful and cost-effective way to improve people's lives. Pharmaceutical treatments have turned dreaded diseases that were once death sentences -- type 1 diabetes almost a century ago or HIV infection more recently are just two examples -- into manageable chronic conditions. Appropriate use of medication has improved the lives of millions of individuals with chronic conditions and prevented hospitalization.

With the growing importance of pharmaceuticals, we've identified two areas that we believe must be addressed in order to unleash a new wave of innovative approaches to pharmaceutical pricing: 1) facilitating more robust communication between health plans and drug developers prior to drug approval and 2) addressing legal and regulatory barriers to value-based payment arrangements.

Improve Communication of Information Needed to Price and Budget

Current regulations can have a chilling effect on pre-approval communications that might be perceived as making claims about the efficacy or safety of a new medicine. These rules have the important goal of preventing the kind of pre-approval marketing that might mislead consumers or physicians. However, questions regarding the interpretation of these regulations and the threat of enforcement under these regulations makes all pre-approval communications a risky proposition for drug developers.

As a result, they are often reluctant to actively help health plans understand the scope of the population that may be served by a drug or to discuss pharmacoeconomic studies that might help establish appropriate reimbursement. Consequently, it's possible that health plans – which must price new drugs well in advance – may be surprised by and unprepared for unexpected cost surges and patient populations presented by the approval of a new drug. This surprise can send shockwaves through the system, with late-breaking, unexpected budget impacts for the government and employers.

Remove Regulatory Barriers to Value-Based Payment Arrangements

There are at least two areas that currently pose a challenge to more robust value-based payment arrangements: anti-kickback statutes and government best-price rules. Anti-kickback statutes are in place to stem fraud and abuse by prohibiting arrangements where organizations or individuals could receive inappropriate incentives to use one product over another. This is a well-intended protection, but in the case of value-based payment, such statutes might discourage drug developers and health plans from working together to create incentives structured around adherence to and efficacy of a drug in certain patient populations. We need to create a pathway that preserves these rules but allows for innovative arrangements that clearly benefit the health care system and patients.

At the same time, drug developers are also required in some cases to offer Medicaid programs their “best” price—regardless of arrangements in other markets that may be structured very differently than a traditional price-per-dose. For example, a drug developer may have agreed to pay a rebate of 40 percent to a private health plan for every individual who does not respond to therapy, while charging full price for patients who did respond. That same drug company might then be required to offer certain government programs a 40 percent rebate across the board. This lack of flexibility makes it very difficult for drug developers to enter into more innovative partnerships focused on creating value.

These policy ideas are the beginning of a necessary partnership. Lilly and Anthem both want the same thing for patients—to have access to new, innovative medicines now and into the future. By bringing together best ideas from our organizations, we will be able to more successfully provide access to state-of-the-art treatments to improve health and cure illness.

To read the two detailed policy papers outlining these proposals, please visit www.ThinkAnthem.com and <https://lillypad.lilly.com/>



While the rest of the healthcare system is paying for value, payments for drugs largely continue to be stuck in a 20th century construct that focuses on price, regardless of the health outcomes of each patient. Anthem and Eli Lilly and Company are collaborating to help accelerate the transition towards a value-based system with policy proposals that will help drive payment innovation. Read more at [ThinkAnthem](#) and [LillyPad](#).

Facilitating Open Communication About Emerging Therapies

Eli Lilly and Company and Anthem | January 29, 2016

The following memorandum outlines Eli Lilly and Company and Anthem's joint perspective on creating a legislative or regulatory exemption that would allow manufacturers and health plans to communicate about emerging products prior to U.S. Food & Drug Administration (FDA) approval.

POLICY GOAL: Clarify federal law to confirm that manufacturers may speak openly with health plans about drugs going through the FDA approval process, particularly with regard to product efficacy, safety, and pharmacoeconomic information.

Background and Context

Aligning drug coverage decisions with rate development and budgeting timelines – that is, making a new drug available within an insurance premium that reflects expected spending on that drug, among many other factors – requires thoughtful synchronization over a several-month period. Two recent developments have created an environment where this alignment is difficult for health plans¹, state and federal governments, and manufacturers to achieve, ultimately creating downstream consequences for consumers.

First, with changes to commercial insurance processes included in the Affordable Care Act, insurance rates in most lines of business (including the individual market, employer market, Medicaid, and Medicare) are set – and unchangeable – well before the coverage year begins (see Appendix A). Accurate rate development relies on detailed assumptions about the use of healthcare services, including prescription drugs. Manufacturers are the best source of reliable and accurate clinical and pharmacoeconomic information about emerging therapies, but face significant restrictions on communicating to plans information about not-yet-approved products. When plans cannot accurately account for a drug when setting rates, they may overestimate the drug's cost, setting premiums higher than is ultimately needed to cover the costs of the drug, and perhaps discouraging some consumers from purchasing coverage. Alternatively, plans might underestimate the cost of the drug, thus setting premiums that do not cover costs. As a result, plans may need to consider mid-year solutions to control budgets like more stringent utilization management criteria.

At the same time, the new U.S. Food & Drug Administration (FDA) "breakthrough" therapy designation process means that blockbuster drugs will likely be moving more efficiently through the development, review, and approval processes. While more rapid approval of breakthrough medicines means that these products are available to consumers sooner, health plans, employers, and state and federal governments have less time to plan for their utilization. "Breakthrough" drugs by definition offer significant benefits for consumers – the designation is granted when preliminary clinical evidence shows they may represent substantial improvement over available therapies for treatment of a serious condition – but can have significant budget impacts on health plans, employers, and state and federal governments. Given current health plan rate development and budgeting requirements, some of the most promising new medicines are most vulnerable to timing challenges and their potential implications for patient access.

Clarifying that manufacturers and health plans may discuss critical scientific evidence and other drug features (e.g., dosage, pharmacoeconomic information, and clinical indications) for products under FDA review would encourage these discussions, allowing health plans to better anticipate effects on the target patient population and consider available pharmacoeconomic and efficacy data. Stakeholders could design the clarification to preserve FDA's interests, as discussed below.

¹While this document references health plans throughout, the policy solution would also aid other stakeholders including pharmacy benefit managers and certain providers who purchase drugs.

Existing law and regulations are intended to achieve a very specific and important goal: preventing the marketing of a drug before FDA determines that it is safe and effective for its intended use. However, the FDA regulations on this subject, namely 21 C.F.R. § 312.7, are broadly written and could be interpreted to sweep in beneficial and otherwise non-harmful communications. Health plans have long used sophisticated methods for assessing the evidence base and patient access considerations for new medicines, and are well positioned to assess manufacturer-generated evidence and consider any existing limitations in evidence available prior to FDA approval. However, given the lack of clarity on the boundaries of permissible, pre-approval scientific exchange, manufacturers are hesitant to discuss clinical data or pharmacoeconomic information until FDA approves a product.

While pre-approval communication between manufacturers and health plans should explicitly be lawful and permissible, policy safeguards could prevent the distribution of pre-approval information to other audiences, such as patients, who may not be equipped to interpret it. For example, manufacturers and health plans could enter into appropriate non-disclosure agreements. As is the case today, a therapy would not be used prior to FDA approval under the proposed solution, and health plans would still have ample opportunity to review the label post-approval. In addition, manufacturers might commit to follow up with health plans when necessary to correct any assumptions made in pre-approval discussions that materially differ from the final product labeling agreed with FDA.

Facilitating Open Communication

Removing the existing uncertainty about as to when and how manufacturers and health plans can communicate about certain critical clinical and safety aspects of a drug's attributes before FDA approval could benefit patients, health plans, state and federal governments, employers, and manufacturers. Patients could directly benefit in the form of less restricted access to new medicines and more predictable trends in insurance rates from year to year. Health plans would have additional, directly relevant information when establishing rates and benefits for the upcoming year. Manufacturers would have the opportunity to engage in more timely conversations with health plans, providing targeted and well-timed information that may be helpful when price negotiations occur.

The Unfortunate Lack of Communication: A Case Study

The Case

- Health Plan X is developing its rate for the upcoming year. Final rates are due in April.
- Health Plan X knows that breakthrough Drug Y is undergoing FDA review. Drug Y is expected to significantly improve outcomes and experience for patients with a certain type of cancer. However, Health Plan X does not know which patients will be eligible to take Drug Y. The manufacturer of Drug Y is unable to discuss Drug Y's target patient population or potential price with Health Plan X.

| Options for Health Plan X | OPTION ONE: Health Plan X Overestimates Utilization of Drug Y | OPTION TWO: Health Plan X Underestimates Utilization of Drug Y |
|---------------------------------------|---|---|
| Health Plan X Pre-Approval Assumption | Health Plan X assumes that 3 percent of its members will take Drug Y during the year. Health Plan X also estimates price and factors these assumptions into rates and thus into the budgets of health plans, employers, state and federal governments. Health Plan X assumes that 1 percent of its members will take Drug Y during the year. Health Plan X also estimates price and factors these assumptions into rates and thus into the budgets of health plans, employers, state and federal governments. | Health Plan X assumes that 1 percent of its members will take Drug Y during the year. Health Plan X also estimates price and factors these assumptions into rates and thus into the budgets of health plans, employers, state and federal governments. |
| Drug Y is Approved | Drug Y is approved by the FDA in September. Based on the FDA-approved label, only 1 percent of Health Plan X's members are candidates for Drug Y. | Drug Y is approved by the FDA in September. Based on the FDA-approved label, 3 percent of Health Plan X's members are candidates for Drug Y. |
| End Result | Health Plan X overestimates the aggregate costs associated with Drug Y and develops rates that are higher than they would have been, had Health Plan X had access to more complete information. Fewer consumers purchase coverage because rates are higher than they should have been, and other areas of employer, state and federal budgets are potentially unnecessarily cut. | Health Plan X underestimates the aggregate costs associated with Drug Y and develops rates that do not adequately reflect actual costs. Health plan X and its customers (employers, state and federal governments) more seriously consider aggressive utilization management criteria and stakeholders scramble for mid-year solutions. |

FDA's interests would be protected as well. Manufacturers would continue to have the same strong incentives to seek FDA approval, as commercialization would continue to be dependent on it. Further, new guidance could contain explicit safeguards to protect patient safety and to ensure that communications are truthful and non-misleading, and do not compromise FDA's interest in ensuring the safety and effectiveness of new medicines. For example, manufacturers could include prominent disclaimers on data shared with health plans, making it clear that the data are not FDA-approved. A more detailed analysis of potential stakeholder impacts is included in Appendix B.

Therefore, policymakers and regulators should clearly acknowledge through clarification of federal law and regulations that manufacturers may communicate with health plans about drugs undergoing FDA review, including potential indications, clinical performance and pharmacoeconomic information.

Existing Legislative and Operational Barriers

Current rules prohibit manufacturers from communicating promotional claims of a drug's safety or efficacy for an investigational use, and manufacturers must avoid commercialization of the drug before it is approved for commercial distribution.² FDA's chief concern is that such communication may undermine the approval process, as products' safety and efficacy are not considered to be established until FDA grants marketing authorization. Further, FDA is concerned that pre-approval communication could create confusion if stakeholders share safety and efficacy information that is not ultimately included in the FDA-approved label. Currently, an existing regulation provides that:

A sponsor or investigator, or any person acting on behalf of a sponsor or investigator, shall not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug. This provision is not intended to restrict the full exchange of scientific information concerning the drug, including dissemination of scientific findings in scientific or lay media. Rather, its intent is to restrict promotional claims of safety or effectiveness of the drug for a use for which it is under investigation and to preclude commercialization of the drug before it is approved for commercial distribution.³

However, targeted pre-approval conversations between manufacturers and health plans are not inherently promotional, and in the absence of definitive negotiations or a signed agreement, such conversations would also not amount to commercialization. In any event, use of a medical product would not be allowed prior to FDA approval. While such conversations are not clearly covered or prohibited by existing legislation or regulations, ongoing concerns about FDA's interpretation have a chilling effect on industry and create a compelling need for clarification.

Key Considerations for Implementation

Clarifying manufacturers' right and ability to communicate with health plans about certain pre-approval, product-specific information raises several practical considerations. First, key stakeholders (i.e., FDA, manufacturers, health plans) would need to define the specific types of information that are critical to inform desired discussions. We expect this information would include data from pivotal Phase III clinical trials (supported by substantial evidence) or pharmacoeconomic data (supported by competent and reliable evidence). Additionally, stakeholders should consider what limitations and parameters must guide these discussions (e.g., the discussions should be limited to indications undergoing FDA review, should be within a certain time period of the expected PDUFA date, should be subject to confidentiality restrictions, and should contain appropriate disclaimers). Manufacturers and health plans would need clear guidance from FDA on these topics, as well as compliance and oversight expectations.

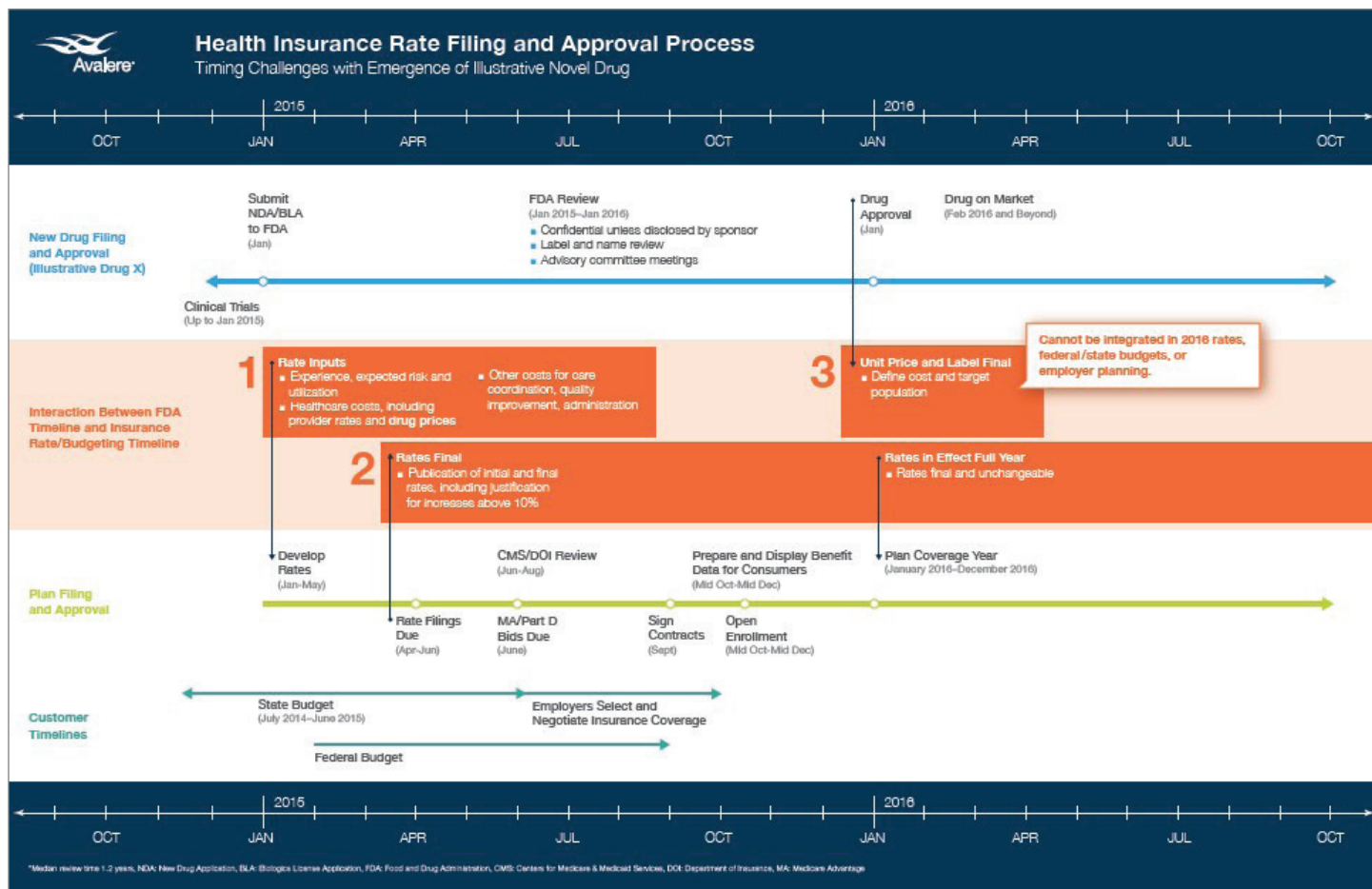
FDA's existing regulatory framework for post-approval communications – that they be truthful and non-misleading – offers one potential path forward for setting expectations and guardrails for pre-approval discussions.⁴ Applying a standard to pre-approval communications that is similar to the truthful and non-misleading standard applied to post-approval communications has several important benefits. Notably, this would ensure consistency over time (pre- and post-approval). Key stakeholders are already familiar with the standard, which would facilitate implementation of such an approach for pre-approval discussions. By applying a familiar but rigorous standard to pre-approval communications, while clarifying the parameters of these discussions, FDA can inject greater consistency into its regulatory framework and encourage richer discussions among stakeholders, ultimately benefitting patients and other stakeholders.

²21 C.F.R. § 312.7

³21 C.F.R. § 312.7

⁴See 21 U.S.C §§ 352(a), 321(n); 21 C.F.R. § 202.1(e)(3)(i).

Appendix. Health Insurance Rating Filing and Approval Process





While the rest of the healthcare system is paying for value, payments for drugs largely continue to be stuck in a 20th century construct that focuses on price, regardless of the health outcomes of each patient. Anthem and Eli Lilly and Company are collaborating to help accelerate the transition towards a value-based system with policy proposals that will help drive payment innovation. Read more at [ThinkAnthem](#) and [LillyPad](#).

Promoting Value-Based Contracting Arrangements

Eli Lilly and Company and Anthem | January 29, 2016

The following memorandum outlines Eli Lilly and Company and Anthem's joint perspective on creating legislative and regulatory options designed to promote value-based contracting arrangements for manufacturers and commercial health plans.

POLICY GOAL: Create a policy environment conducive to allowing health plans and manufacturers to enter into a variety of value-based contracting arrangements, aligned with the shift toward value-based payment and the goal of promoting access to high-value care. This may include creation of legislative/regulatory exceptions for Best Price and all other relevant government pricing calculations and requirements as they relate to products sold or transferred under value-based contracts, as well as additional safe harbors to the federal Antikickback Statute (AKS) that protect value-based contracts from AKS liability.

Background and Context

Policymakers and industry are looking for opportunities to drive quality, create savings, and slow cost growth in the healthcare system. In particular, stakeholders are increasingly focused on value and increasing the use of treatments, products, and services that are both clinically effective and efficient. In fact, by 2018 the Department of Health & Human Services intends to link 80 percent of Medicare payments to value, and 50 percent to alternative payment models like bundled payments.¹

While there has been substantial innovation in how health plans and the government reimburse for hospital and physician payments (with physician payments moving further in this direction following the recent Medicare and Children's Health Insurance Program (CHIP) Reauthorization Act), payment for prescription drugs is often based on more traditional outcomes (e.g., volume of product purchased). Given the role that prescription drugs play in the treatment of and spending for many complex and chronic conditions, health plans and manufacturers seek greater opportunity to align payment with quality, accountability, and coordination. Ultimately, these arrangements can encourage access to high-value medicines and treatments and ensure that patients are getting the best value for their healthcare dollars. However, existing legal and regulatory barriers are stifling this innovation.

Traditional drug pricing contracts typically establish a fixed price for the product that remains in place throughout the benefit year. This may include flat pricing (e.g., price per unit) or volume arrangements. For example, a health plan and manufacturer may agree that if spending for a particular medicine exceeds a certain level, the manufacturer will offer the health plan a discount or rebate on the unit price. In contrast, value-based arrangements may condition payment or drug price based on patient-level clinical or economic outcomes (e.g., a 1 percent reduction in HbA1c levels for certain patients with diabetes). As illustrated in Appendix A, these arrangements represent a fundamental departure from traditional contracting and may require investment from both manufacturers and health plans. In order to design a contract that makes payment for a therapy contingent on patient outcomes, for example, the manufacturer and the health plan must agree on how to reliably, accurately, and appropriately measure outcomes and categorize patients as "responders" or "non-responders." In addition, both plans and manufacturers need to designate staff to monitor and execute the agreement, a further investment by both parties.

¹HHS.gov. "Better, Smarter, Healthier: In historic announcement, HHS sets clear goals and timeline for shifting Medicare reimbursements from volume to value." 26 January 2015. Available at: <http://www.hhs.gov/news/press/2015pres/01/20150126a.html>

Value-based arrangements allow both parties to share in the risk associated with individual patient outcomes and spending for a particular medicine. These contracts offer important benefits for consumers, health plans, and manufacturers. Consumers, in particular, may enjoy earlier or less managed access to new medicines when payments are aligned with value. Over time, identifying and encouraging use of the highest-value products could both improve patient outcomes and curb healthcare spending growth. Although manufacturers and health plans seek opportunities to invest in these innovative models, existing legislation and regulations raise concerns, including:

- **Anti-Kickback Statutes:** Federal and state fraud and abuse laws are designed to protect patients, health plans, and the healthcare system overall from fraud, waste, and abuse. The Anti-Kickback Statute (AKS) prohibits offering or receiving remuneration (broadly defined) to induce or reward referrals for items or services paid for by federal healthcare programs. Statutory and regulatory safe harbors protect certain arrangements from AKS liability, but it is unclear how enforcement agencies would apply these safe harbors to value-based arrangements.² AKS violations carry significant financial and other penalties.
- **Government pricing:** Manufacturers are required to report pricing data to the federal government to determine Medicaid rebates; Medicare Part B payment rates; the 340B program ceiling price; and the maximum price that certain government agencies can be charged. Because these reporting requirements did not foresee and were not designed to be compatible with value-based contracting, they could make it exceptionally difficult for a manufacturer to enter into a value-based contract. For example, current Medicaid rebate regulations would require that rebates paid to a commercial health plan in the context of a single value-based contract be made available to Medicaid programs, even though Medicaid programs would not be subject to the key design features of the value-based arrangement (for high level examples of value-based arrangements, please see Appendix A).

In order to capitalize on the potential of value-based arrangements for consumers, industry, and other healthcare stakeholders, policymakers should adapt standards related to kickbacks and government pricing to accommodate these novel contracts. Absent such clarification, legislation and regulations that reflect traditional contracting will continue to impede innovation.

Promoting Value-Based Arrangements

The goals of value-based contracting approaches align with the shift toward high-value care. Such agreements seek to make more efficient use of healthcare resources, potentially reducing costs throughout the system, encouraging use of the most efficient and effective care, and improving patient outcomes.

Clearer safe harbors and guidance for all stakeholders could promote the adoption of value-based models. For example, stakeholders could benefit from:

- Expansion or creation of new statutory or regulatory safe harbors, including by the OIG, to the AKS that more clearly protect innovative, value-based contracting arrangements (under a defined set of requirements);
- Amendments to the statutory and regulatory definitions of certain prices reported to the government (e.g. Best Price) to define the terms for excluding payments made pursuant to value-based contracts;
- Regulations clarifying how manufacturers can incorporate value-based contracts in their price reporting calculations; and,
- Pilots or demonstration programs with commercial health plans that adapt the government pricing rules to test how value-based contracts impact reported government price figures, and in turn, Medicaid rebate amounts and 340B ceiling prices.

Existing Legislative and Operational Barriers

FRAUD AND ABUSE

As described above, current fraud and abuse guidance may have a chilling effect on value-based arrangements. For example, if a manufacturer and health plan entered into an arrangement under which the manufacturer accepted risk for treatment failure (e.g., the health plan would only pay for a drug for patients with positive treatment outcomes), this could be viewed as remuneration offered to encourage the health plan to favorably cover the manufacturer's product. Additionally, the OIG has not issued sub-regulatory guidance addressing value-based contracting arrangements, leaving stakeholders with little to no insight on OIG's position on the risk of fraud and abuse they pose.

To alleviate stakeholder concerns related to fraud and abuse, regulations and guidance could be updated to establish regulatory³ safe harbors, and the OIG could update guidance⁴ in order to explicitly protect these arrangements when certain criteria are met. Congress could also consider establishing a statutory safe harbor. The safe harbor eligibility criteria can be designed to minimize risk of fraud and abuse in these arrangements. For example, the OIG could require that value-based payments be determined in advance, and could not vary during the term of a contract.

³42 C.F.R. § 1001.952

⁴66 Fed. Reg. 23731 (May 5, 2003)

GOVERNMENT PRICING

Manufacturers' government price reporting obligations may also have a chilling effect on the development of value-based contracts. Largely, this is a result of the way pricing, discounts, and contracting arrangements affect government price reporting, and in turn, manufacturer obligations under a variety of federal programs.

Best Price and Average Manufacturer Price

Implications for Best Price are the most immediate, important factor to consider with respect to manufacturer incentives created by value-based contracting. Best Price is the pricing benchmark Medicaid uses to ensure state Medicaid programs never pay more than the lowest price offered for a particular therapy. Best price is set based on the single "lowest price available from the manufacturer during the rebate period to any entity⁵ in the United States."⁶ Best Price is affected by manufacturer rebates, discounts, or other price concessions to commercial health plans, and setting a new Best Price can lead to significantly increased Medicaid rebate and 340B program liability for manufacturers. Under the current regulations, payments from manufacturers to health plans under a value-based contract would almost certainly need to be included in Best Price calculations. For example, if a manufacturer offered a health plan a rebate equal to 60 percent of the list price of a product for each enrollee who did not respond to treatment, and negotiated a payment rebate equal to 20 percent of the list price for patients who did respond, the 60 percent rebate would determine the product's Best Price for all patients. If the list price were \$1,000, this would result in a Best Price of \$400 (assuming that there were no greater discounts/rebates in the market; if so, Best Price would be even lower). As the example below shows, reductions in Best Price can result in significant Medicaid rebate and 340B liability.

| | List Price | AMP ⁷ | Best Price (BP) | Medicaid Rebate Amount per Unit (AMP-BP) ⁸ | 340B Ceiling Price (AMP – Medicaid Rebate Amount) |
|---|------------|------------------|-----------------|---|---|
| Without value-based rebate (example) | \$1,000 | \$950 | \$700 | \$250 | \$700 |
| With value-based rebate (including patients who do not respond to therapy) | \$1,000 | \$950 | \$400 | \$550 | \$400 |

* Assumes no additional "inflation-based" rebate

These reductions may create negative returns on value-based contracts for manufacturers. The Best Price statute and regulations could be updated 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 and 340B ceiling prices.

Further complicating compliance with the price reporting rules is the fact that many value-based arrangements could constitute "bundled arrangements," which require complicated re-allocation of price concessions, either across products or across periods, and trigger additional disclosure obligations.

Average Sales Price

Best Price is not the only price point that would be impacted by value-based contracts. For medical benefit drugs (in general, those that are physician-administered), manufacturers are required to report Average Sales Price (ASP) to the Centers for Medicare & Medicaid Services (CMS) on a quarterly basis; ASP is used to set Medicare Part B reimbursement rates.⁹ ASP is defined as "the manufacturer's sales to all purchasers...in the United States for a drug or biological in the calendar quarter [excluding exempted sales] divided by...the total number of such units of such drug or biological sold by the manufacturer in such quarter."¹⁰ Like Best Price, rebates to commercial health plans are included in ASP, but unlike Best Price, ASP is an average price and is not determined by a single sale.¹¹

Manufacturers of medical benefit products may be concerned that substantial rebates offered to commercial health plans under value-based contracts would reduce ASP, and in turn, Medicare Part B reimbursement rates for their products. Relatedly, CMS may substitute Average Manufacturer Price, or AMP, for ASP under certain conditions. AMP is also used in determining Medicaid rebates, and a product's

⁵With certain exceptions, including most government purchasers and Part D plans.

⁶42 C.F.R. § 447.405

⁷Assumes AMP = 95% of List Price.

⁸As BP is used in this particular example, it is assumed that this price (AMP-BP) is greater than statutory requirements in this particular scenario.

⁹42 U.S.C § 1395w-3a(b)(1).

¹⁰42 U.S.C § 1395w-3a(c)(1).

¹¹42 U.S.C § 1395w-3a(c)(2). The ASP statute references the statutory definition of Best Price in defining what rebates and discounts are excluded from ASP; in other words, the same rebates and discounts that are excluded from Best Price are also excluded from ASP. Therefore, changes to the definition of Best Price would also impact manufacturer's ASP calculations.

340B ceiling price. Accordingly, it will be critical for policymakers to address the implications of value-based arrangements for government prices in a consistent and comprehensive manner.¹²

OPERATIONAL COMPLEXITY

Value-based arrangements are complex, and manufacturers and health plans will need to align expectations with respect to desired outcomes, data collection, appropriate safeguards for patient privacy, and other factors. Manufacturers and payers are willing to work through these challenges, but the up-front investments necessary to make value-based arrangements succeed underscore the importance of appropriate regulatory and financial protection.

Manufacturer reporting and operational responsibilities under current pricing rules also pose a challenge. Accurately calculating and reporting government pricing figures are extremely complex tasks. Many pharmaceutical manufacturers expend significant resources on these activities. Value-based arrangements, in which the ultimate “price” of a product may not be known for a substantial period of time after the product is sold, would introduce significant operational complexity into these calculations and potential for legal ramifications. Additionally, many innovative contracting arrangements do not price products on a per-unit basis; for example, a course of therapy or treatment regimen price may be used instead. Incorporating non-unit based pricing into government pricing calculations may be very complex.

Key Considerations for Implementation

Several strategic considerations are critical to ensure the success of value-based contracts under a new regulatory paradigm. First, value-based contracts must be properly defined through federal regulation in order to accommodate existing and future goals. The definition will need to establish whether a value-based arrangement must have certain core features (e.g., risk sharing) in order to be eligible for any legislative and regulatory carve-outs, and, if so, what those core features are. While defining such an arrangement is necessary to ensure stakeholders have a common understanding of the arrangement, the definition will need to be sufficiently flexible to allow for potential innovative structures that have yet to be developed.

The government should simultaneously assess how best to update relevant laws and regulations in order to accommodate these innovations. For example, regulators could develop a template memorandum of understanding for payers and manufacturers to use, or a sample agreement between a manufacturer and the government that would appropriately exclude value-based pricing concessions from reporting. In addition to updating directly relevant laws and regulations (e.g., those related to pricing), regulators will need to consider whether existing fraud, abuse, and monitoring paradigms protect all stakeholders – including patients – impacted by value-based arrangements.

Finally, it will be important to allow for the emergence of value-based arrangements as part of the broader health system transformation and assure continued efficiency for government programs and patient access. By creating an environment in which value-based contracts are permitted, increased collaboration between health plans and manufacturers to enter into value-based contracts presents a significant opportunity to drive quality and access, create savings, and slow cost growth, aligned with the value-based shift in the overall US healthcare system.

¹²It is important to note that AMP for 5i products, which are infused, instilled, implanted, injected, or inhaled products that are generally not dispensed through a retail community pharmacy, includes additional rebates. Further, if a particular product is not sent through a distributor for 90% of gross sales, then the Non-Federal Average Manufacturer Price (NFAMP) is affected as payer discounts are factored in due to the 90-10 rule.

Appendix A

The below graphic depicts the level of risk on behalf of the health plan and manufacturer as well as the degree of difficulty of implementation of value-based contracting arrangements.

| | Traditional Discounting | Conditional Payment | Value-Based Arrangements |
|----------------------------|---|--|---|
| General Description | Drug price is established prior to coverage and fixed for the benefit year | Payment contingent on certain short-term health outcome or evidence collection target | Reimbursement is tied to clinical or process outcome at the individual patient level |
| Key Inputs | Negotiated discount or rebate | Pre-determined goal for a defined patient population (e.g., short-term treatment goal such as persistence) | Pre-determined goal for a defined patient population (e.g., 1% reduction in HbA1c, performance versus competitor, delay in disease progression) |
| Key Outcomes | Varies (e.g., flat pricing, volume of drug purchased) | Attainment of treatment goals or collection of additional evidence through research | Patient-level clinical or process outcome (may occur after benefit year ends) |
| Example | <ul style="list-style-type: none"> Market share-based rebating or price-volume arrangements Utilization cap or manufacturer-funded treatment initiation | Coverage/payment with evidence development or conditional treatment continuation | Manufacturer provides rebate on products purchased for patients who fail to achieve desired outcome seriously consider aggressive utilization management criteria and stakeholders scramble for mid-year solutions. |

Degree of Difficulty and Risk *The specifics of any type of value-based arrangement vary, and are negotiated by the plan and the manufacturer*

Source: J Carlson, et al. "Linking payment to health outcomes: A taxonomy and examination of performance-based reimbursement schemes between healthcare health plans and manufacturers." Health Policy. 2010 Aug;96(3):179-90.

Appendix B

The following tables outline the statutes and regulations by topic area as relevant for this memorandum.

Fraud & Abuse

| Legislative or Regulatory Change Desired | Corresponding Statute/Regulation |
|--|----------------------------------|
| Addition of statutory safe-harbor to existing language | 42 U.S.C. § 1320a-7b |
| Addition of regulatory safe harbors to existing language | 42 C.F.R. § 1001.952 |
| OIG guidance to pharmaceutical manufacturers should be updated | 66 Fed. Reg. 23731 (May 5, 2003) |

Government Pricing

| Definition Referenced | Corresponding Statute/Regulation |
|--|----------------------------------|
| Statutory definition of Best Price | 42 U.S.C. § 1396r-8 |
| Regulatory definition of Best Price | 42 C.F.R. § 447.505 |
| Statutory definition of ASP ¹³ | 42 U.S.C § 1395w-3a |
| Regulatory definition of ASP ¹⁴ | 42 C.F.R. § 414.804 |

¹³Note that if the statutory definition of BP is updated to exclude value-based payments, they will also be excluded from the statutory definition of ASP due to the fact that the ASP statute cross-references the BP statute

¹⁴Note that if the statutory definition of BP is updated to exclude value-based payments, they will also be excluded from the regulatory definition of ASP due to the fact that the ASP regulation cross-references the BP statute