Health Care Cost Trends

Society of Actuaries Pharmacy Partnership Forum

"Reimagining Pharmacy Finance"

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Pharmacy Partnership Forum

"Reimagining Pharmacy Financing"

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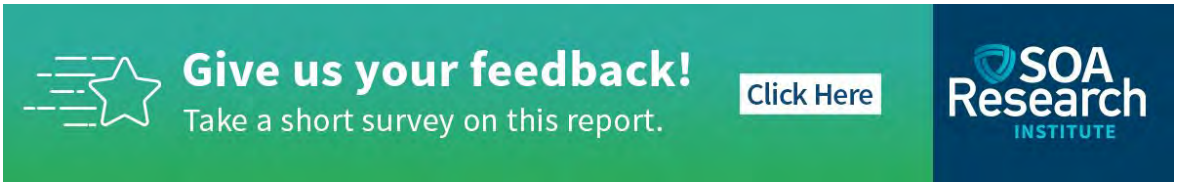

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Pharmacy Partnership Forum

"Reimagining Pharmacy Financing"

Section 1. Executive Summary

Pharmacy prices are top of mind for many consumers, policymakers, and payers. While there have been many efforts to reduce pharmacy costs over the years, many believe these efforts only helped us cope with the symptoms of the problem without providing a comprehensive cure for the underlying causes of this problem. Although these solutions partially assist some stakeholders, they fail to deliver a complete solution. The Society of Actuaries Health Section sponsored this Pharmacy Partnership Forum to gather multi-disciplinary experts in the pharmacy ecosystem to discuss three key questions at the root of this problem: 1) "How should we define the value of a prescription drug?" 2) "How should we measure the value of a prescription drug, and do we have the data and analytical methods we need?" and 3) "How should we scalably and meaningfully apply the answers to pharmacy financing?" This report shares the insights and learnings that emerged from this group of health economics outcomes researchers, clinical pharmacists, medical doctors, health actuaries, benefits consultants and brokers, and their collective thoughts on advancing this exploration for society's benefit.

1.1 ABOUT THE FORUM

This forum arose from research from an earlier forum co-sponsored by the Society of Actuaries (SOA), Initiative 18|11: What Can You Do About the Cost of Healthcare?[1]. As the name implies, the purpose of that conference was a multi-disciplinary discussion about the cost of healthcare in the United States (about 18% of gross domestic product at the time) relative to the cost of healthcare in other developed nations (about 11% of gross domestic product at the time) and their comparative outcomes. As a result of that conference, the SOA and its primary co-sponsor, the Kaiser Family Foundation, produced a conference report, presented the results at several industry conferences, and launched several work streams to study key areas in more detail.

One of these workstreams focused on pharmacy and resulted in two series of published articles: "Actuarial Perspectives on Prescription Drug Financing"[2] and "Additional Actuarial Perspectives on Prescription Drug Financing."[3] These publications provided valuable information about how the pharmacy financing system works today, including the drug development process, regulatory process, consumer impact and economic impact. The themes that emerged from those publications were to increase transparency, encourage competition, align stakeholder incentives and mitigate total cost of care increases. Those themes led to identifying the three questions and the concept of this multi-disciplinary forum to address them. The forum was held in Rosemont, Illinois on March 15, 2023.

The rules for the forum were simple. First, participants agreed to follow the SOA's anti-trust guidelines[4]. Second, opinions expressed by participants were deemed to be opinions of the participants and not those of the SOA or the forum facilitator, Axene Health Partners, LLC. Finally, participants agreed to follow the Chatham House rules, which encourage open and free dialogue by allowing participants to use the information provided during the discussion as long as the name or affiliation of the participant is not disclosed[5]. The participants did agree to disclose that they attended.

1.2 DISCUSSION SUMMARY

The discussion summarized the challenges of the U.S. healthcare system and its pharmacy ecosystem and identified its various stakeholders with their sometimes competing and sometimes aligned priorities. The professional disciplines (e.g., health economists, clinical pharmacists, health actuaries, medical doctors, etc.) supporting those stakeholders and their different approaches to defining and measuring value were discussed and appreciated.

Themes of increasing transparency, encouraging competition, aligning stakeholder incentives, and mitigating total cost of care increases, which emerged from previous Society of Actuaries research, united and catalyzed the discussion. The desire to restore patient-centricity in the U.S. healthcare system also emerged as a galvanizing theme, and participants saw the recent and upcoming advances in precision medicine and digital health applications as a means to drive that.

Using more scalable and meaningful alternative payment methods (APMs) was identified as a possible approach to aligning stakeholder incentives while increasing transparency and encouraging competition. Such APMs could use metrics such as total cost of care and extension of life to allow for scalability. These models could also consider other measures of value (such as productivity, pain relief, daily activities, caregiver savings, etc.) by translating these measures to monetary value and including them in ROI equations. A new concept, total risk analysis, will also provide a valuable tool for negotiating reimbursement methods. Total risk analysis measures both the projection risk and the random variation risk in a manner that allows each party to answer questions like "what are the chances we will lose more than $1 million under this arrangement?".

1.3 NEXT STEPS

Continued collaboration across professional disciplines is necessary for transformative solutions in our healthcare system to accomplish the unifying themes of increasing transparency, encouraging competition, aligning stakeholder incentives, and mitigating total cost of care increases. Participants identified numerous next steps as important for carrying forward the collaboration that was in evidence at the Forum:

- Sharing summaries of the Forum discussion through this report and panel presentations at numerous upcoming professional meetings in 2023 (e.g., Society of Actuaries' Health Meeting and ImpACT Conference, Academy of Managed Care Pharmacy Nexus Meeting, National Association of Specialty Pharmacist, The Professional Society of Health Economics and Outcomes Research meetings, etc.).

- Providing case studies for real-life examples of meeting key objectives like aligning stakeholder incentives and mitigating the total cost of care. One of the participants mentioned that Kaiser may be a good starting point for this work.

- Society of Actuaries research project on whether there are meaningful differences in total cost of care among patients of different prescription drugs in the same therapy class after adjustment for demographic and risk differences in the patient populations.

- Research projects and pilot APM agreements between stakeholders that explore broader "value stack" return-on-investment (ROI) models as a basis for upside-and-downside risk and value sharing. In order for the numerator in the ROI equation to be comprehensive, some value terms may require translation from non-monetary measures to monetary measures.

Section 2. Lessons Learned from Initiative 18/11

The discussion began with a brief recap of important lessons learned from Initiative 18/11. In each case, the "lesson" is simply a true statement that must be considered in developing potential solutions.

2.1 THE HEALTH CARE IDENTITY

In one sense, the health care identity is pretty simple: One person's income equals another person's costs. The issue is, however, how each party reacts in a given situation. If a provider raises prices, how can the payer offset those costs? How will the provider respond to the lost income if a payer reduces its costs?

One example of this dilemma that arose during the discussion was the sustainable growth rate provision of the Balanced Budget Act of 1997. The legislation's goal was to ensure that the average Medicare expense per participant did not exceed the increase in GDP. If this goal was not met during a year, the law prescribed a lower increase in Medicare payment rates the following year to compensate. However, with only one exception, every year Congress passed a physician update, or "doc fix," as it is often called. The physician updates ranged from 0.0% to 7.5% (far exceeding the GDP growth rate benchmark), except for 2002, when the update was -4.8%. The Medicare Access and CHIP Reauthorization Act of 2015 replaced the sustainable growth rate formula. Among other things, this legislation introduced the concept of using alternate payment methods for Medicare physician reimbursement. Alternate payment methods are sometimes called value-based reimbursements and will be discussed in more detail below.

Repealing the sustainable growth rate formula exemplifies the health care identity pushing stakeholders to a more innovative approach to containing costs. The discussion, however, also included potential examples of times when the health care identity may push stakeholders to simply move money around. For example, there was a lively discussion about whether or not providers charged more to commercial payers to offset lower-than-expected income from Medicare and Medicaid. There was no general agreement on that point, but there was agreement that a sound structure is necessary to achieve cost savings.

2.2 LONG POCKET/WRONG POCKET

Many treatments require considerable up-front costs, but the benefits are not fully realized until years later. When the benefits are realized, the patient may no longer be with the original payer. For example, a patient may have received treatment for smoking cessation, which, as one attendee pointed out, usually takes about four years to reach a break-even point. By then, a patient in a typical employer group plan may have left the original plan and moved to another employer. The second employer will reap the benefit for that patient (long-term healthcare cost savings) for which the first employer made the investment (smoking cessation program costs).

Several attendees pointed out that, in this example, the first payer could also benefit from a smoking cessation program offered by some other payer for other patients that move to the first payer. In that case, the costs would, perhaps, more or less even out for the payers across the smoking cessation and similar programs.

2.3 THE 5/50 PRINCIPLE

Several important studies have shown that healthcare costs follow the Pareto Principle, sometimes called the "80/20" rule. According to this principle, most healthcare costs can be attributed to a relatively small proportion of the population, known as the concentration percentage. In the United States, roughly 50% of healthcare costs can be attributed to 5% of the population, thus the 5/50 rule[6]. At one point, there was a hope that healthcare costs could be lowered by "hot-spotting" or concentrating resources on just the top

spenders. The problem with that approach is the considerable turnover in the top 5% each year[7]. Much of the turnover is due to the episodic nature of healthcare. For example, once a patient has received a costly, successful transplant, the patient returns to a healthier, lower-cost status. Recently, many new, expensive gene and cell therapy techniques have been introduced, driving up the costs for the top spenders. The most common diseases for persistent top spenders include multiple sclerosis, HIV, cystic fibrosis, and certain cancers[8]. Many of these diseases require expensive, ongoing pharmaceutical treatment.

The increase in high-cost drugs can be financially disastrous for small, self-insured employers and smaller managed care organizations, even those with a stop-loss program. Stop-loss plans often exclude named individuals with certain conditions from coverage. This practice is often referred to as "lasering." Attendees agreed that new, innovative stop-loss and reinsurance programs were needed, while recognizing that such innovations address how risk is shared more efficiently but not the root causes of the risk.

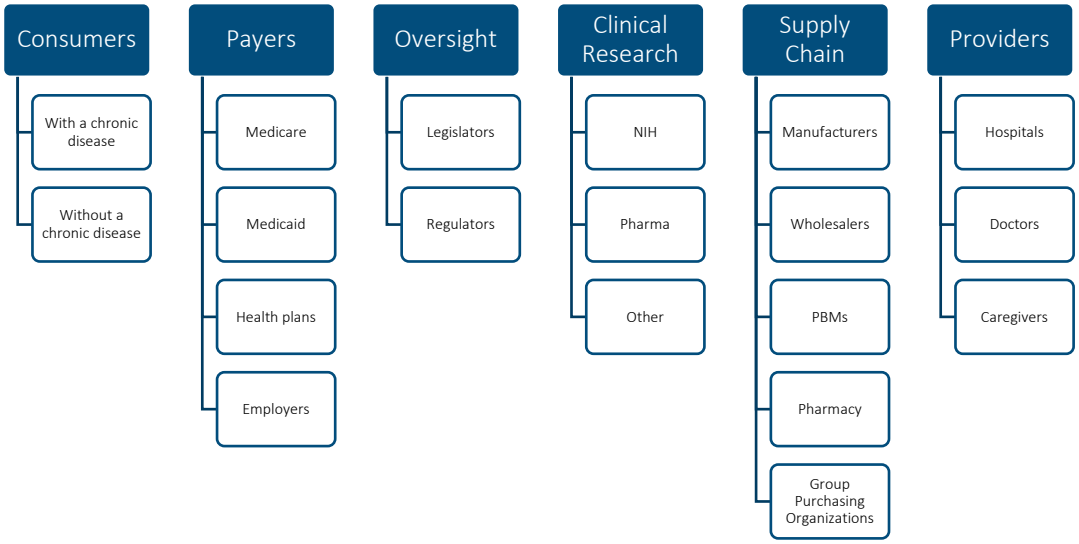
Section 3. Defining Value

Like many things in life, each stakeholder has a different view of how to define value. During the discussion, attendees presented several ways to view value.

3.1 STAKEHOLDERS

There are several ways to curate stakeholders for discussion purposes. Many attendees recommended describing stakeholders by how they relate to the patient. Others recommended thinking of stakeholders in terms of how they relate to society as a whole. This view would focus on the patient and reflect factors like increased productivity. For this discussion, the transactional approach shown in figure 1 was used.

Figure 1.
DIRECT STAKEHOLDERS



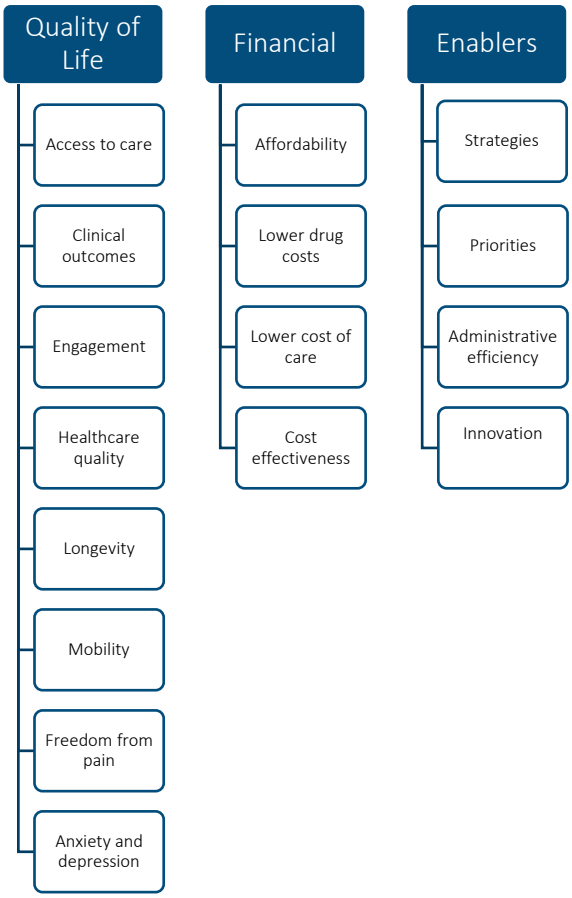
One note. The image shown in figure 1 includes just the direct stakeholders. Many other vested parties support each of these stakeholders. For example, each direct stakeholder may rely on employees, brokers, and consultants to perform their duties. From a financial perspective, taxpayers and investors are a necessary part of the process.

3.2 VALUE FRAMEWORKS

Each stakeholder has a view of value as defined by their specific needs and goals. In each case, the stakeholder's perspective may include many different elements of value. Since the attendees at this conference were multi-disciplinary, the discussion was based on the value framework shown in figure 2. This framework focuses on identifying specific value elements to determine if that element can be measured or at least clearly defined.

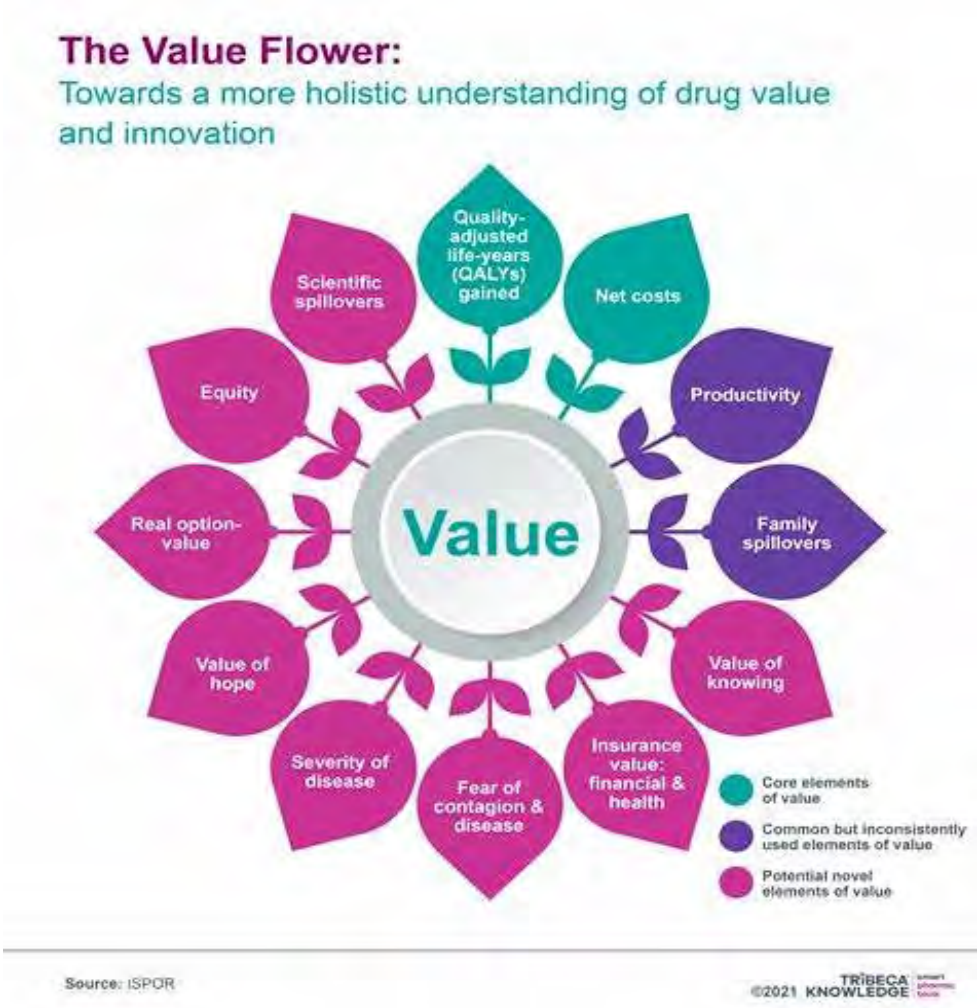
One participant pointed out that, for employers, the bottom line is the cost of prescription drug benefits, though the context of the well-being and productivity of their employees also matters. Another participant emphasized that, for the pharmacy and therapeutics committees of pharmacy benefit managers, the comparative outcomes and costs of prescription drugs are important. It was also mentioned that value definitions sometimes vary in countries and societies and by other "books of business" within a country. In the United States, Medicaid populations differ from Medicare or commercial populations. The difficulty in applying more typical value definitions for end-of-life treatments or palliative care was also discussed.

Figure 2.
TRANSACTION VALUE FRAMEWORK



Several participants mentioned that they prefer to use the Professional Society for Health Economics and Outcomes Research value flower framework. This organization was formerly known as the International Society for Pharmacoeconomics and Outcomes Research (ISPOR), so the framework is often called the ISPOR value flower.

Figure 3.
THE ISPOR VALUE FLOWER



Under this framework, core value elements include quality-adjusted life years (QALYs) gained and net costs per QALY. QALYs combine the benefits of life extension and the quality of life into a single number, the cost per quality-adjusted life year gained. Depending on the specific analysis, there is often considerable overlap between the value elements in a QALY calculation and those described under the quality-of-life domain in figure 2. Similarly, there is a potential for significant overlap between the "net costs" petal on the value flower and the financial domain of the framework shown in Figure 2.

There are also some key differences between the two value frameworks. Figure 2 shows a specific domain for "enablers" or techniques used by stakeholders to guide the process, an important part of this discussion. Similarly, the value flower includes some potential novel elements of value, like "the value of knowing" and the "value of hope," which are not included in the Figure 2 framework. One value element that generated much discussion was equity, which is not included in the Figure 2 framework. While there was general agreement that equity is a key goal for most stakeholders, there was a question of whether equity was a value element per se or a matter of how value is distributed among the stakeholders.

3.3 INNOVATION

Many participants stressed the value of innovation with an emphasis on high-end technological advances. Specifically, one attendee speculated that CRISPR, a state-of-the-art gene therapy process, will be obsolete in ten years. At the other end of the spectrum, there was some conversation about food as medicine. To some extent, this concept has already been implemented through programs like Geisinger's Food Farmacy program. Such programs intend to address obesity, a key risk factor associated with chronic diseases. In both cases, attendees expressed concerns that current cost-effectiveness techniques would be inadequate for these innovations.

Section 4. Measuring Value

One of the key questions addressed in this forum was, "How should we measure the value of a prescription drug, and do we have the data and analytical methods we need?" That is a broad question so, of course, the answer depends on the purpose of the underlying analysis. The discussion focused on two key types of analytics: coverage decisions and reimbursement analytics. In both cases, the attendees agreed that, while a solid foundation is in place, there are areas for improvement.

4.1 VALUE-SPECIFIC MEASUREMENT

In making coverage decisions and negotiating prices, an important element of that process should be measuring the appropriate value elements. Some elements of value, such as those in the financial domain, lend themselves to quantification more easily than others. For example, payers can access claim cost data at the patient-drug level using the in-house administrative systems used to pay claims. Total costs (or allowed amounts) are the total payments made to the pharmacy, plus the cost share paid by the patient.

However, one key data element, rebates, is missing from that equation. Rebates are amounts paid by pharmaceutical manufacturers to pharmacy benefit managers ("PBM") for their drugs' inclusion on formularies, inclusion on preferred tiers of formularies and/or for resultant market share levels of their drugs within a therapy class on "books of business" managed by that PBM. They are reimbursed to a PBM in lump sums many months after the prescriptions have been filled. The PBM then allocates all or a percentage of those rebates back to the various payer clients (e.g., health plans, employers, governments, etc.) that comprise that "book of business" based on the contractual terms between that PBM and each of those payer clients.

In many cases, rebate information is considered proprietary, so little or no information is available for analysis outside the negotiation process. According to a 2016 Altarum report, rebates for Medicare programs are over 30% of the total costs[9]. Similarly, some techniques for measuring value elements in the financial domain are more straightforward to estimate than others. Specifically, techniques for measuring the impact of a specific drug on the total cost of care are not well-developed.

Some elements in the quality-of-life domain are also relatively easy to quantify if the data is readily available. For example, information about clinical outcomes, like a lower A1C level for diabetics, can be quantified using electronic health records. Although providers generally have some access to electronic health records, payers historically have not. Many value elements, like mobility and freedom from pain, are measured using a survey instrument describing the patient's condition. For example, patients are often asked to rate their pain on a scale of 1 to 10, with 10 being the highest. This information is usually memorialized in the patient's chart, but may or may not be collected for more general analysis.

Different quality and value measures were discussed, including HEDIS measures, various clinical measures like HbA1c and glucose levels, frequency of various types of diagnostic testing, Medicare Stars measures, etc. It was pointed out in the discussion that value is often still defined by proxy measures and measures of activities in the absence of broadly scalable and measurable outcome endpoints.

Based on the research done for the discussion framework document and the discussion during the conference, the general conclusion is that, for each quality of life and financial element, there is a way to measure that element, but no measure meets all the needs of all the stakeholders. For example, affordability can be measured in terms of the average cost per course of treatment. That said, the average cost of a treatment may be affordable to some stakeholders but not others, depending on the patient's income level.

4.2 NEW DRUG COVERAGE DECISIONS

When a new drug enters the market, each payer must decide whether to cover it and to which formulary tier (and associated patient copay or cost share amount) it belongs. In some countries, the starting point for the coverage inclusion/exclusion analysis is a health technology assessment (HTA). An HTA is a formal, scientific process of synthesizing and evaluating the evidence for a new drug[10]. The purpose of an HTA is to enable stakeholders to make the optimal decision about how to use the drug. HTAs usually answer key questions like[11]:

- Does the drug work?
- Is it safe?
- Is it cost-effective?

When a new drug is introduced, information is usually limited to the results from the clinical trials, including any information obtained through surveys. The EQ-5D[12] instrument is often used in HTAs. The instrument for evaluating healthcare interventions measures six dimensions: mobility, self-care, usual activities, pain/discomfort, anxiety, and depression. However, it does not consider other value elements, such as longevity and cost-effectiveness. In contrast, most Health Technology Assessments (HTAs) utilize the Quality-Adjusted Life Year (QALY) thresholds to establish cost-effectiveness.

QALYs reflect both the extension of life and the quality of life to which a drug contributes. For example, if a drug extends a patient's life by one year and that year is spent in perfect health, then the QALY = 1.0. Similarly, if the drug only extends the life by one year, but the quality of life is measured at a 50% level, then the QALY = 0.5 (1 year x 50%). The cost per QALY gained is the ratio of the annual cost to the incremental QALY gained. For example, if a drug costs $100,000 per year and has an incremental QALY of 1.0, the cost per QALY for that drug would be $100,000 ($100,000 ÷ 1.0). On the other hand, if the incremental QALY gained is 0.5, then the cost per QALY for that drug would be put at $200,000 ($100,000 ÷ 0.5). In some countries, coverage decisions are based on QALY thresholds. For example, if the payer's QALY threshold is $100,000, the drug would most likely be covered if the incremental QALY is 1.0 or higher, otherwise it would not be covered. Or, to state it another way, if the cost per QALY is less than $100,000, then the drug would most likely be covered. It would most likely not be covered if it is over $100,000.

In recent years, QALYs have been criticized for several reasons. In part, that controversy centers around the fact that QALYs are used primarily for allocation of resource decisions and do not reflect an individual patient's value. For example, some patients may be willing to pay $200,000 for a drug if it means reaching an important milestone, like the birth of a grandchild, a wedding, or a graduation[13].

Additionally, this excerpt from a "Rare Disease Community Statement on Drug Pricing Policy Priorities" from the EveryLife Foundation" expresses other concerns with QALYs: "Limitations include that calculation of the Quality-Adjusted Life Year (QALY) gained is widely considered to be discriminatory towards patients with disabilities, patient heterogeneity and subgroup analyses are often not considered, and additional elements of value afforded by innovative therapies, such as increased productivity and reduction of caregiver burden, are often not included."

Translation of non-monetary value measures to a monetary value can often be accomplished. For example, the reduction of a pain scale measure can be tracked, and the cost of effective pain relievers can approximate the cost of that reduction. Measures of activities of daily living (ADLs) exist, and the cost of obtaining assistance with those ADLs can also be quantified and, thus, serve as a monetized value for improvement in ADLs. As various types of values are translated to monetized measures, they enable those measures of

incremental value to be compared to their incremental cost and are described as a "return on investment" (ROI) over a specified period. ROI comparisons are common decision-making tools for payers.

Translating non-financial measures of value into an ROI (return on investment) representation and then analyzing how much of the increased value and increased costs (thus the incremental ROI) go to each stakeholder can provide valuable insight. A couple of the participants mentioned they are developing such a "value stack" and shared the following image to help describe it.

Figure 4.
VALUE STACK.

Later-in-life treatments (like many oncology medications) may warrant different measures of value that are more defined by measures of extension of life, such as "overall survival" or "progression-free survival" rates.

4.3 PRICE NEGOTIATIONS

In the United States, the price of a drug is based on contractual terms negotiated between the payer (e.g., self-funded employer, health plan, government payer, etc.) and the PBM. Those terms are affected by negotiations between the PBM and its network pharmacies and between the PBM and pharmaceutical manufacturers (or rebate aggregators). For the most part, negotiations are done annually. When a drug is first introduced, the only data available comes from the clinical trial studies and, perhaps, the experience of similar drugs. Based on this limited information, each party can project the expected financial and quality-of-life impacts.

Like any projection, the actual results will almost certainly vary from the expected results. The variance may be because the original projection assumptions or methods were inadequate or because of random statistical variation. Using a relatively new concept, total risk analysis, the analyst can estimate several key statistics

like “what are the chances this estimate will be off by more than $1 million?”. The following year, each party will have additional information available based on the experience during the first year. Therefore, the projections will presumably be less susceptible to flawed assumptions or methods in the second and subsequent years.

Section 5. Applying the Answers

The next question posed to the group was, "How should we scalably and meaningfully apply the answers to pharmacy financing?" And, will the proposed solutions meet the objectives identified in the SOA's Pharmacy Research: 1) increase transparency, 2) encourage competition, 3) align stakeholder incentives, and 4) mitigate total cost of care increases?

5.1 WHAT ARE WE DOING NOW TO REDUCE COSTS, INCREASE QUALITY?

Payers utilize formularies to define which drugs are covered and which are not. Non-covered drugs require the patient to pay the full cost of the prescription, while covered drugs enable the patient to receive their prescribed medication while paying a flat-dollar copayment amount or a percentage of coinsurance calculated as a defined percentage of the total cost (or allowed amount), which usually includes a discount from the pharmacy's "off-the-shelf" price, which has been negotiated with the pharmacy by the PBM on behalf of the payer for the pharmacy to be "in-network."

Most payers steer patients to the lowest-cost drug for a specific condition using plan design. In this case, the payer sets up a formulary that categorizes drugs by tier. The lower the tier, the lower the patient's cost-share is. For example, the generic version of a drug may be in the lowest tier with a copay per script of $10, but the brand equivalent may be in a higher tier with a $25 copay per script. This can help encourage the use of lower-cost medications among therapeutically-equivalent alternatives.

The tiering also increases competition among therapeutically equivalent brand medications as their manufacturers negotiate rebates with PBMs and payers to gain lower-tier placement and, therefore, the utilization encouragement that helps them drive more market share within the therapeutic class.

PBMs and payers have developed clinical programs to ensure safety and promote cost-effective utilization of prescription drugs from among those options on the defined formulary that applies to the patient. These include prior authorizations, step therapy edits, quantity limits, medication therapy management, concurrent and retrospective drug utilization reviews and other clinical programs.

And yet, over the years, as more and more benefit design tiers and clinical programs are developed and implemented, overall prescription drug spend continues to increase, and the cost burden on patients is still not relieved.

5.2 POLICY SOLUTIONS

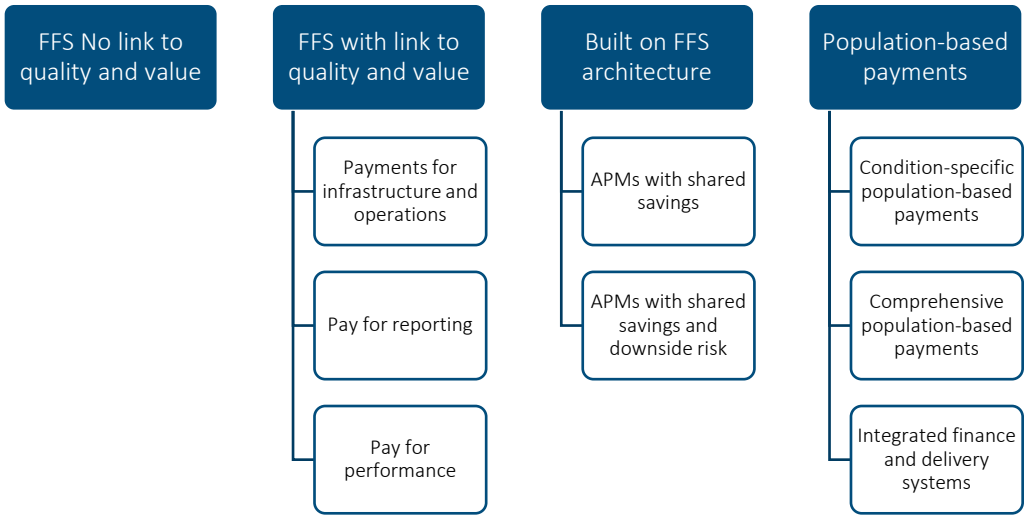
There have been many policy solutions proposed. Various legislative and regulatory efforts to require price transparency, eliminate "spreads," tie prices to different types of international price averages and import medications from other countries have been explored and sometimes implemented.

Most recently, the Inflation Reduction Act, signed into law in 2022, requires drug companies to pay a rebate if they raise prices faster than the inflation rate[14]. The Inflation Reduction Act also permits Medicare to negotiate prices for several costly drugs. Finally, the IRA capped member cost-sharing amounts for insulin at $35 per month for Medicare beneficiaries. There was considerable discussion at the meeting about the various potential implications of the IRA. Will it lead to increased launch prices or not? How will the prices and total drug spend be affected for other drugs in the same therapeutic class as drugs for which CMS negotiates prices? How will it affect drug prices and total drug spend in commercial markets?

5.3 ALTERNATE PAYMENT METHODS

The Health Care Payment and Learning Action Network (HCP-LAN) has developed a framework for classifying alternate payment methods (APM) used to determine reimbursement methods for doctors and hospitals, as illustrated in Figure 5.

Figure 5.
HCP-LAN REIMBURSEMENT FRAMEWORK



Source: APM Framework Refresh White Paper (hcp-lan.org)

Currently, most reimbursement in this framework moves the system away from a fee-for-service (FFS) basis to a basis where providers are rewarded or penalized based on how well they manage cost and quality.

The discussion questioned whether this framework works for doctors and hospitals. One attendee commented that the Medicare Payment Advisory Commission (MedPAC) is considering alternatives. Several attendees expressed concern that the adoption process is taking so long. Another attendee commented that this structure was based on the traditional one-year financing model used for doctors and hospitals, and another commented that, with the patient-physician relationship still at the core, it will be important to influence that relationship when seeking to impact prescription drug spend with alternative payment models. It was also mentioned that "downside" penalties are much more impactful when motivating physician behavior than "upside" bonus potential.

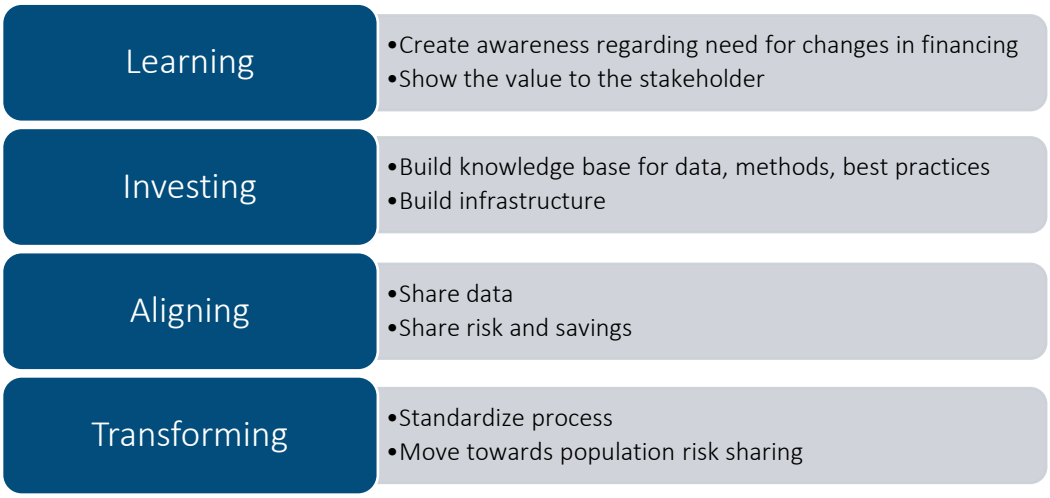
Pharmacy value, however, needs to be measured over several years since the basic concept is commonly "pay me now, and I will save you money later." There was considerable skepticism over how to confirm whether this framework is working as intended over time. Value-based formularies that guarantee total cost per prescription or plan cost per prescription have been available from PBMs for several years, but have not seen significant demand from health plans, employers or government payers or their benefits consultants or brokers.

However, APMs based on an ROI framework outlined in the "value stack" visual using monetary measures (or value measures translated into monetary measures) hold promise as a widely understood comparison tool, and extension of life measures can be applied for therapies treating late-in-life conditions.

5.4 CHANGE MANAGEMENT ROADMAP

The group was in general agreement that, to affect change, there will need to be a roadmap to guide the process, including an understanding of what steps impact change. The starting point for the conversation was a reference to the HCP-LAN roadmap summarized in Figure 6.

Figure 6.
HCP-LAN ROADMAP



Source: 2030_APM_Goals.pdf (hcp-lan.org)

One attendee noted that this roadmap and similar roadmaps were geared towards transitioning established organizations incrementally. In a sense, while promoting change management roadmaps to help existing organizations transition, it is also important to simultaneously take steps to enable and encourage disruptive innovation.

There was considerable discussion around the question "what takes so long?" One participant noted that they had expected to see an increase in APMs following the passage of the Affordable Care Act (ACA) in 2010. Another attendee responded that, on the payer side, most of the resources following the ACA were spent on building the infrastructure needed to meet the new regulatory requirements and administer the new programs. After the passage of the ACA, there was a promulgation of APMs between payers and providers. However, APMs between pharmaceutical manufacturers and payers have not yet seen the same pace of growth.

Section 6. What's Next?

The group moved into the "what's next" conversation, having discussed many different ideas about defining value, measuring value, and identifying and implementing scalable and meaningful solutions for our nation's pharmacy ecosystem. The unifying concepts of promoting transparency, encouraging competition, aligning stakeholder incentives and mitigating total cost of care increases continued to shape consensus, but "the devil is in the details."

Some identified issues require significant infrastructure changes that necessitate policy changes and private investment. Others may give rise to pilot programs and pilot agreements as negotiated between various stakeholders. The logical next step is to present the information to bring about action among those various parties. An article series may be the best way to build knowledge about change management and behavioral finance and how they can each contribute to solutions for our pharmacy ecosystem.

Ultimately, when it came to designing comprehensive solutions, the idea of "blowing everything up and starting over" had some appeal. However, it was acknowledged that the method to achieve that goal was unclear, and the practicalities of providing ongoing patient care made it unrealistic to pursue such an idea.

Empowering patients and placing them at the center of the solution became a desirable starting point. The recent emergence of precision medicine and personalized digital applications for consumers presents powerful potential as advancements in genomic science and technological capabilities gain momentum. Patient permission will be necessary, and industry consolidation across the fragmented genomics and digital health industries will likely contribute much.

Closed systems like Kaiser and others present an opportunity to study best practices. A likely finding would be better-aligned stakeholder incentives throughout that closed system, which points back to one of our unifying themes. Aligned stakeholder incentives defined through scalable and meaningful alternative payment methods based upon broadly adopted definitions and measures of the value of prescription drugs could catalyze the needed systemic change. Multi-year APMs could be designed with increasing magnitudes of upside and downside sharing of value and risk to enable expertise, insight and confidence in the programs to grow over time. The "value stack" described above has the broad applicability to apply in most, if not all, therapeutic areas, while using the basic construct of return-on-investment (ROI) ratios that are understandable and usable for all stakeholders due to their broad use across many industries.

The group concluded that an effective way to begin testing this solution could be by conducting a total cost of care research project. The study would evaluate the total cost of care for patients using various brand drugs in the same therapy class, while accounting for demographic and risk differences among the patient populations. The aim is to determine whether significant differences exist between the drugs. This project will include an example of total risk analysis.

If significant differences are found, they can serve as the foundation for APMs. These models can be broadened to encompass other types of value, such as pain relief, improved daily activities, increased productivity, and caregiver savings, in the numerator of the ROI. This approach can be adopted by parties engaged in agreements where these values hold significance. Translation of measures of those values to monetary measures would be necessary for the ROI model to be applied.

The group discussed disease states where such studies could focus. Initial thoughts included diabetes medications, cardiovascular disease, respiratory conditions and autoimmune disorders. Linking electronic health record data and claim data can also create more predictive power.

Similar studies are warranted on whether different brand drugs in the same therapy class produce meaningful differences in extension of life (patient survival) after adjusting for demographic and risk differences in the drug populations.

Each study could include prototypes of several stop loss and/or reinsurance programs designed to share the involved risks efficiently. Total risk analysis can also help identify and manage the risks.

The group agreed that presentations at various industry meetings (e.g., Society of Actuaries, Academy of Managed Care Pharmacy, National Association of Specialty Pharmacy, The Professional Society for Health Economics and Outcomes Research and others) would help advance the discussion that began at this Forum. Additionally, it would encourage various research projects and program pilots that the group views as essential in identifying and implementing solutions similar to those discussed during the Forum.

SOA-sponsored webinars on point-of-sale rebates could help increase transparency. SOA-sponsored webinars on patient reform could help encourage competition.

Precision medicine and digital health applications could put the patient back at the center of the pharmacy ecosystem. Scalable and meaningful APMs have the potential to bring about greater transparency, competition, and alignment of stakeholder incentives. These methods would be built around comprehensible ROI and extension of life frameworks and aim to reduce the total cost of care increases that the healthcare system currently faces. This approach offers promise in addressing the pressing needs of our healthcare system.

Section 7: Acknowledgments

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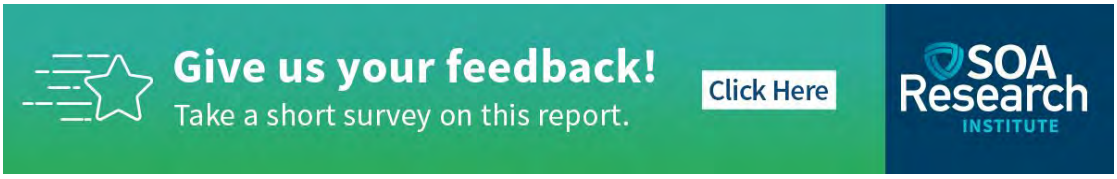

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