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5 Approaches to Improving Value—Provider and Manufacturer Payments

INTRODUCTION

Payment design, coverage policies, reimbursement rules, and other financial incentives and disincentives are powerful motivators when attempting to steer the healthcare system toward more desirable care patterns (Guterman et al., 2009). Experiments with payment design and coverage and reimbursement policies are currently going on in both public and private healthcare sectors, with varying results. Speakers in this session of the workshop explored current payment design experiments and discussed the efficacy of utilizing these reimbursement tools to improve the value received from health care.

In this chapter, Carolyn M. Clancy details the pay-for-performance (P4P) model, an effort to more explicitly link provider payments to quality of care. She highlights the lack of coherent approaches to P4P and the variable success this approach has had in fundamentally changing provider practice patterns. For example, while financial incentives for individual physicians have shown that P4P can induce quality improvements for diabetic patients (Beaulieu and Horrigan, 2005), group-level incentives have had no impact on mammography screening or hemoglobin A_{1c} testing rates (Rosenthal et al., 2005). After underscoring that the current incentive system and healthcare infrastructure fail to accommodate the achievement of real efficiency and quality, she outlines recommendations for rethinking medical training, measurement, system design, and the reward system.

Building on Clancy's recommendations, Donald A. Sawyer identifies how the current healthcare system stymies innovation in product development. He suggests refocusing the myopic view of innovation on the horizon of long-term health improvements and financial savings. Reed V. Tuckson discusses the alignment of manufacturers, technologists, payers, patients, and providers necessary to establish a system that continues to provide incentives for innovation and maintains an open market for the development of promising but unproven interventions. He elaborates specifically on a joint effort between UnitedHealth Group and the American College of Cardiology to develop appropriateness criteria for cardiac single-photon emission computed tomography myocardial perfusion imaging—a new and very expensive technology—based on best evidence as an example of how the interests of diverse stakeholder groups could be aligned.

In conclusion, Steven D. Pearson likens coverage and reimbursement tools to a blunt knife that lacks subtlety in effecting value improvements, but he also expands on coverage innovations in public and private arenas that could sharpen these tools. He specifically describes Washington State's Health Technology Assessment Program—which considers efficacy, safety, and cost-effectiveness in making coverage decisions for all of the state's public programs—and physician edits—which limit the prescription of certain drugs to specific physicians or specialists in an effort to target medications to those patients most likely benefit from them—before elaborating on the future of payment and reimbursement as a tool to improve value.

PAY FOR PERFORMANCE

Carolyn M. Clancy, M.D., Agency for Healthcare Research and Quality

For health reform advocates, this is a very exciting time—one that is driven by a sense of urgency. However, despite many significant efforts at reform, we do not yet have an effective incentive system or a sustainable infrastructure that would allow us to achieve real efficiency and quality. As we search for the answer to "system transformation," I worry about several issues:

1. We create and apply more and more tools to an already chaotic system,
2. We fail to delve into the fundamental problems of healthcare infrastructure, and
3. We confuse short-term tactics and long-term strategy.

Given these difficulties, let me envision what a transformed healthcare system may look like in 10 years. By then we could have a system that:

- Rewards physicians and patients for making the right choices,
- Reports and measures quality electronically,
- Shares best practices rapidly with providers and offers knowledge of how to apply the evidence to individual patients, and
- Focuses increasingly on improving quality and value outcomes for episodes of care.

Pay for Performance

Perhaps seen as one of the keys to system transformation, P4P and value-based purchasing programs have experienced rapid growth in the past decade. There are now literally hundreds of these programs in the private sector. They include any type of performance-based provider payment arrangement, including those that target performance on cost measures. P4P and value-based purchasing extend beyond individual healthcare providers. The Centers for Medicare and Medicaid Services (CMS) and Congress have also extensively discussed launching performance-based reimbursement approaches for hospitals.

However, we still do not know how to design effective pay-for-performance programs, much less how to do so in our very large, very chaotic healthcare system. Some demonstration projects are encouraging (e.g., the Premier demonstration). Yet even the best of these do not yield groundbreaking improvements in patient outcomes. Generally, evaluations of P4P programs find that payment incentives have demonstrated a positive effect, but the effect is relatively modest—and sometimes counterintuitive.

For example, the Agency for Healthcare Research and Quality (AHRQ) funded the Palo Alto Medical Foundation (PAMF) to study different models of P4P. The study involved five sites that have had electronic medical records since 2000 and utilized physician payment tiers based on relative value units of service. Studies of financial incentives for individual physicians have shown that, bundled with other care management tools, P4P can lead to improvement in quality of care for diabetic patients (Beaulieu and Horrigan, 2005). The impact of group-level incentives and a patient registry-intervention system improved documentation of tobacco use but led to no change in the provision of quitting advice (Roski et al., 2003). Group-level incentives also led to small increases in cervical cancer screening but no change in mammography screening or hemoglobin A_{1c} testing rates (Rosenthal et al., 2005). In this study, since the largest relative improvements were seen in those with higher baseline performance, this raises additional questions of how best to distribute the rewards. That is, should already (relatively) high performers receive the largest rewards—or those who improve the most?

This research on P4P has additionally shown that the frequency of payment by itself may not make a difference in performance. In the context of organizational-level quality improvement efforts, relatively small financial incentives to individual physicians have limited incremental

effects on well-established measures. Interestingly the PAMF has also found some spillover effects, where improvements occurred in both incentivized and nonincentivized measures. However, we do not fully understand the processes underlying this outcome and need to learn more about why these spillover effects occurred in order to capitalize on their potential.

AHRQ's quality report last year found that overall quality of care improved in all U.S. populations and settings by 2.3 percent (Agency for Healthcare Research and Quality, 2007). Unfortunately, health costs concurrently increased 6.7 percent. You do not have to know about technical quality measures to see the problem. Something clearly must be done not only to reduce the costs of care but also to improve clinical outcomes. Don Berwick often says that our payment system is not just quality neutral, it is actually pretty toxic. It is easy to make glib statements that our current reimbursement policies reward volume rather than value. Yet those rewards translate into income for a lot of people who are doing very well in the current system. Making dramatic changes in the reward system will be, to say the least, challenging.

Challenges and the Road Ahead

How do we transform a chaotic system that accounts for 16 percent of our economy? We need a road map. We need to rethink our training, measurement, and system design. We also need to change our reward system.

Our challenges include engaging the research and provider communities in developing quality and value measures quickly while creating a sustainable infrastructure for collecting, analyzing, and disseminating information about performance and outcomes. Gaps in value-based measures, measures across episodes of care, and patient-centered outcomes need to be addressed. Incentives must align rewards with quality and value. In one promising activity, the Bridges to Excellence program has tried to determine what it would take to build at least part of the needed infrastructure that would make pay-for-performance work. This includes exploration of cost-savings distribution plans with doctors who deliver high-quality care, such as lowering rates of avoidable hospital admissions.

The evolution of our healthcare infrastructure to a learning healthcare system—one in which real-time feedback on quality creates value for providers and patients—is not possible today. We know that people will not continue to provide data to a collection system or value the feedback they receive unless it is timely and relevant. Take Hospital Compare, a public reporting system of how well hospitals care for patients with certain medical conditions or surgical procedures. When a hospital currently sends its reports to CMS, it takes nine months to get feedback—much too long to imagine that the data will have an impact on quality. As a result, people on the front lines of care delivery have no sense of how their daily work connects to those report cards.

We also will need policies and regulations for information governance because patient-centered assessment and improvement require data sharing and care coordination. Right now the mindset and relevant laws are framed around paper medical records (or their digitized incarnation) and reflect the limitations of these records. We cannot begin to collect the kinds of information that would inform pay-for-performance or allow the creation of a learning healthcare system without clear policies on data ownership, the rules for sharing data, and protocols for providing feedback to patients and doctors in real time.

Recently, several colleagues of mine published an article in the *Journal of the American Medical Association* (Dougherty and Conway, 2008) that discussed the time lag between new biomedical breakthroughs and their widespread application to clinical care. Take, for example, the 25-year delay in getting consistent, appropriate use of β-blockers for patients after heart attacks (Lee, 2007). In order to transform the system into one without delays in the translation of research to

practice, healthcare providers must align with the research enterprises that are trying to improve health care.

More research and better research will not help us obtain better health care unless such research focuses on top priorities and the results are linked strategically to an infrastructure that helps us scale both promises and best practices.

INCENTIVES FOR PRODUCT INNOVATION—PRODUCT MANUFACTURER PERSPECTIVE

Donald A. Sawyer, J.D., AstraZeneca Pharmaceuticals

We all know that America is at a critical crossroads in health care. We can continue with business as usual and suffer the consequences, or we can take on the issues at the root of the problem. We're here today because we have chosen the latter, and we understand that to be part of the solution, we must be part of the conversation.

Like every other party at the table, we have opinions on how health care *should be* structured. We believe that any reform package should promote market competition that leads to improved health outcomes. It should maintain and enhance patient safety. It should expand coverage for the uninsured. Healthcare reform should provide incentives for product innovation—specifically innovation that paves the way to pharmaceutical breakthroughs.

Incentives for innovation are imperative to patient health and the future of American health care. I am fortunate to be part of an organization whose priorities are to keep people healthy and to keep care accessible, while also promoting an environment that encourages innovation. As a company, we believe that a good healthcare system should support these goals. Yet the reality is that the system in place doesn't do that very well.

The question is: How are we going to change it? How are "we"—we meaning the pharmaceutical and biological industry and all payers—going to ensure that innovative, meaningful medicines are discovered, developed, and delivered to the right patients, to ensure optimal patient outcomes, and ultimately to improve the healthcare system?

A Word About Research and Development and Return on Investment

Before we discuss ways to work collaboratively to improve the healthcare system, it is essential to talk about what really goes into innovation. Pharmaceutical firms spend most of their resources on drug development. To develop a single drug takes anywhere from 10 to 15 years. So if we started work on a new drug today, that would put us at the finish line in 2023—by then, Barack Obama would qualify for Medicare.

To bring that single drug from lab to pharmacy costs more than $1 billion in current dollars, not to mention the investment in drugs that never make it to market. For every 5,000 compounds tested, only five ever make it to clinical trials, and only one receives FDA approval (Pharmaceutical Research and Manufacturers of America, 2008). Let me give you a real example. You've probably never heard of a diabetes drug called Galida. You have not heard of it because after spending tens of millions of dollars and dedicating hundreds of employees to bring it to market, we decided not to continue with the process. Why? Because we did not believe it offered a significant benefit for patients over existing therapies. Of the drugs that are approved and do make it to market, only 2 in 10 will ever recoup their cost of development.

Instead of focusing on innovation in the short term through the lens of a microscope, if we—and all players in the system—were to view innovation through a telescope and take a long-term view, the rewards of the time and financial investment of bringing a new drug to market would be substantial. For example, for every $1 spent on cholesterol medicines, more than $5 is saved on

disease-related costs. With diabetes, the return is even greater. For every $1 spent on diabetes medicines, the system realizes a $7 return on investment (Pharmaceutical Research and Manufacturers of America, 2008).

Neither Payers nor Manufacturers Are Demanding Change

Innovation is integral to reducing our healthcare costs and improving patient health, but our current system provides little incentive for innovation.

Over the years, American health care has evolved into a system whose primary goal is not patient health outcomes, but rather containing short-term costs. If achieving better patient outcomes were the goal, the painstaking, time-intensive research and development just described would have all of the encouragement and backing it needs. Unfortunately, it does not. The current system does little to provide for innovation, and we all have equal responsibility for this problem: payers, manufacturers, and policy makers.

The fact is that both payers and drug manufacturers are responsible for the current situation. Both parties are living in a short-term environment focused on delivering results to our shareholders. However, if we maintain this short-term perspective, we cannot unlock the true potential of innovation.

For the last 20 years, the relationships between payers and the pharmaceutical industry have been focused largely on financial arrangements that are short term and transactional in nature. Manufacturers and payers engage in contract negotiations intended to agree on a price that will enable patients to access our products. These contracts also drive market share. This is logical behavior for companies focused on creating shareholder value. Yet as we know, the value of innovative therapies is not often realized within a single budget cycle.

Florida's Medicaid program and Pfizer tried to address this issue through an innovative program that ended abruptly in 2005 due to legislative changes. Pfizer guaranteed $33 million of savings over two years. Instead of paying supplemental rebates to secure placement of its products on the Medicaid formulary—money that does not always end up going toward health care—Pfizer implemented a disease management program. The true impact on savings and patient outcomes was never realized (Pfizer, 2004).

Today, we are beginning to recognize that if we take a longer-term view and hold each other accountable for delivering on health outcomes in addition to our quarterly financial results, we can do a better job for patients. So what can we do to foster a long-term, holistic approach that encourages increased innovation?

At AstraZeneca, we are starting to talk with like-minded payers about concepts that will transform our business relationships, have a positive impact on patient health, provide the incentives for pharmaceutical innovation, and still deliver on payer business results. These objectives do not have to be mutually exclusive.

Some of these concepts include tying discounts to metrics other than market share, such as medication adherence, lower copays for essential medicines, and attainment of treatment goals. We are finding that we will have to try some of these concepts by piloting them with payers who have integrated medical and pharmacy data and are comfortable with defining and assuming risk. Gradually, we are starting to see signs of a shift to a focus on outcomes. Today, leading-edge companies such as Pitney Bowes and Marriott are experimenting with the concept of "value-based insurance design," a model that encourages the use of high-value products and services when the benefits outweigh the costs. The success has been tangible, creating a real savings for those organizations willing to step outside of the box and do something different.

Pitney Bowes, for instance, reduced copayments for drugs prescribed for diabetes and asthma. As reported in the several publications including the *Wall Street Journal*, the company realized a $1 million net savings in the first year from reducing complications that are common in patients with those diseases (Fuhrman, 2004, 2007; Mahoney, 2005).

A growing number of employers—Marriott, Mohawk Industries, University of Michigan, and even my own employer AstraZeneca—are beginning to incorporate the lessons learned form Pitney Bowes and other experiments, such as the well-known Asheville Project, into their own health benefit plans. Some health insurers are too. This kind of innovation on the part of payers provides the incentive for innovators to bring to market high-value healthcare products, be they pharmaceuticals, devices, or biologics.

The advantage of value-based benefit designs such as these is that they not only allow companies to better manage their costs, but also result in a healthier, more productive workforce, which, for any company, *should be* the objective of health care.

Where Do Providers and Patients Fit In?

We can talk as much as we want about paying for outcomes, but it does not really become meaningful until we start talking about the potential to improve the health of patients.

In reality, the current system focus on cutting costs in the short term over achieving long-term results is standing between providers and their patients and better outcomes. I will share one example. Earlier this year, a Wilmington, Delaware, cardiologist was invited to give an overview of acute coronary syndrome to members of one of our development teams. During the question-and-answer session, the doctor was asked whether he had the autonomy to use the treatments he thinks are most appropriate for the individual patient. The short answer was “no.”

The doctor responded that today he is confronted with reimbursement methods that work against each other and ultimately do not put the patient first. Formularies require the use of generic statins and make branded statins, which are often more effective especially in high-risk patients, more difficult to prescribe. At the same time, the Centers for Medicare and Medicaid Services is asking doctors to report on outcomes such as: Are these same high-risk patients reaching certain cholesterol goals? This doctor knows that generic options are not likely to get his high-risk patients to that goal, putting the doctor in a frustrating spot.

In short, we have a payment system that manages inputs instead of encouraging outcomes. What is clear to this doctor is that we need a system that focuses on patient outcomes, not input components. The prevailing “one-size-fits-all” approach does not allow doctors to do what they are trained to do: exercise their best clinical judgment for the individual patient.

This physician is frustrated because he is aware of the inherent conflict of competing reimbursement methods. The patient’s behavior, however, is shaped by those financial incentives—unaware that the benefit design may not support his or her health and welfare—and all too often leads to negative health consequences.

Let me explain what I mean. Over the last decade, patients have been asked to shoulder a greater percentage of their prescription drug costs. On average, the out-of pocket copayment for prescription drugs is 22 percent. For doctors’ visits, it is 10 percent, and for hospital stays, the copayment is 3 percent. There is ample evidence that patient cost sharing lowers spending and decreases pharmaceutical utilization. Evidence also shows that these effects are more pronounced as the copayments increase.

Yet does cost sharing decrease overall healthcare costs? Evidence from studies by Dana Goldman of RAND (Goldman et al., 2004), Mark Fendrick of the University of Michigan and Michael Chernew of Harvard University (Chernew et al., 2008), and others (Kessler et al., 2007) tell us

that cost sharing decreases patient compliance with essential medications in chronic disease and actually increases utilization of other services, such as hospital admissions and acute doctor or emergency room visits.

Conclusion

What I have described today is a current system that is unsustainable: a system where a patient sees no other choice than to split pills in two or not take them at all. The economic downturn will only intensify the patient's dilemma. As former U.S. Surgeon General C. Everett Koop said, "Drugs don't work in patients that don't take them" (Osterberg and Blaschke, 2005).

The current system simply will not drive the incremental *and* breakthrough innovation we need to continue to bring patients groundbreaking, and sometimes lifesaving, therapies. We are quickly approaching a stalemate where the current system will either drive or stop innovation. The risk, then, is not finding potentially lifesaving therapies or changes that could drastically improve patient outcomes. Modern medicine has advanced tremendously over the last 30 years, to the point where we are asking, "Do you really need another drug to treat hypertension or diabetes? Can this disease really be managed any better at this point?"

Before answering, a statement attributed to Charles Deull, Commissioner of the U.S. Patent Office in 1899, should be considered: "Everything that can be invented has been invented."

We cannot afford to be short-sighted.

Every day at pharmaceutical companies, hundreds of decisions are made around innovation. When we invest, there is no guarantee that the scientific investigation will result in products we can bring to the market. Frequently we conduct the research and analyze the data only to conclude that our investment in a particular molecule will not yield the expected value. However, to continue to forge ahead, we need a system where that risk and those "go/no-go" decisions, such as the ones involving Galida, are ultimately rewarded. We need a system that rewards innovative therapies. We also need a system that is focused on delivering the greatest long-term value to patients.

> Our timing is right. To echo the words and the charge of now former Health and Human Services Secretary Michael Leavitt when he spoke in this very room, we are called "to be an instrument of change and to try and solve the issues resulting from the current Medicare payment system. . . . [We are called] to work together to propose a system that will not compromise patient outcomes for short-term savings and will not compromise innovation to make short-term budgets." (Leavitt, 2008)

INCENTIVES FOR PRODUCT INNOVATION—PAYER PERSPECTIVE

Reed V. Tuckson, M.D., FACP, UnitedHealth Group

In my work at UnitedHealth Group, I am routinely excited by the opportunities that we have to facilitate access to the full range of comprehensive health and medical services that people need. Coordinating wellness, prevention, early diagnostic, therapeutic, and restorative care services is exciting and stimulating. However, the context for our work is shaped significantly by the dramatic escalation in healthcare costs and the related challenges to affordability faced by millions of our customers and other Americans. As such, we have a responsibility to work with all healthcare stakeholders to ensure that new innovations in health and medical care delivery work effectively, are cost-effective, and are used in a manner consistent with scientific evidence and expert physician-derived clinical guidance.

Unfortunately, our experiences mirror the published literature that describes significant waste of expensive healthcare assets (Fisher et al., 2003; Welch et al., 1993; Wennberg et al., 2007). This is unfair to people such as our small-employer customers, many of whom may have mortgaged their homes two or three times to make a go of it and who tenuously employ five or six other dependent people. So, while I am excited about innovation and the potential that it can deliver, we also have a responsibility to be extremely vigilant in determining what is adopted and how it is utilized within the total context of the delivery system.

It is clear from our experience that the existing care delivery infrastructure is suboptimal in this regard in several important ways:

- The availability of a robust and clinically relevant basic science research agenda;
- The ability of expert physicians and medical specialty societies to analyze and translate science into clinical guidance;
- The ability to define specific population groups for which new knowledge and innovations are appropriate;
- The dissemination of knowledge to the profession and its incorporation into appropriate clinical practice through mechanisms such as continuing medical education and information technology; and
- The available support for appropriate patient decision making in the context of the patient-physician relationship.

Given this context, we have important work before us. First, the Institute of Medicine needs to be more active in providing guidance for the prioritization of prevention research on the nation's research agenda. It is frustrating and inappropriate that so few of our research dollars are devoted to population, community, and individual prevention. It seems that somehow we have made a national decision to value high-intensity and complex medical innovation much more than finding and testing new and creative ways of preventing disease and promoting wellness. Given the escalation of preventable chronic disease and its associated costs, we need a much more robust research base regarding what works in prevention and the cost-effectiveness of those interventions.

Second, the ability to prioritize the agenda and the infrastructure for the conduct of clinical trials remains suboptimal. Inadequate funding for high-value opportunities and insufficient supply of researchers with available time are but two of the challenges to this infrastructure.

Third, as widely recognized, comparative effectiveness research is essential. However, support for these studies and analytics needs to include not only *clinical* comparisons of new innovations against existing treatment interventions in the context of the total management of a condition, but also *cost-effectiveness* comparisons. Additionally, care should be taken to ensure that the funding mechanisms for new comparative effectiveness studies do not threaten the viability and centrality of the Agency for Healthcare Research and Quality (AHRQ) in its leadership role for health services research.

Fourth, medical specialty societies are poorly prepared and significantly underresourced to translate clinical research into guidance and performance assessment measures. The culture of medicine requires expert physician leadership and peer-to-peer consultation in determining clinical guidance. For example, I am excited about the work we are doing with the American College of Cardiology to support the creation of appropriateness criteria, clinical guidance, performance assessment, and continuing education in the use of the rapidly growing and expensive single-photon emission computed tomography myocardial perfusion imaging (SPECT MPI) for cardiac imaging. Unfortunately, very few other societies are positioned to carry out

these types of analyses expeditiously and to do so in a cost-effective way. Therefore, it is important that AHRQ be provided with funding that can be used to support our specialty societies to accomplish this important work. If physicians are going to exert the leadership that we expect, our society needs to support their societies with the necessary resources.

Finally, we also need to educate the American people to better prepare them to make the personally appropriate choices regarding the use of new and expensive interventions, while also being respectful of the economic consequences of ill-advised decisions. In this new genetic era, the decisions and choices that people are required to make will be more complex than ever. Unfortunately, they are poorly prepared to do so. It is in everyone's interest to better assist people in their role as responsible stewards of their own health, in addition to the use of expensive technologies.

In conclusion, innovation in any field brings with it excitement and optimism. In health care, at its best, innovation can help people to live healthier lives, prevent hospitalizations, and reduce the misery and economic consequences of debilitating disease. However, innovation, for its own sake, is not particularly exciting, especially if it contributes irresponsibly to misaligned priorities and waste of precious healthcare assets. As such, all stakeholders in health care have a responsibility to think carefully about what we are trying to achieve, the priorities for the use of resources, and the accountability that each sector has for maximizing access to affordable, quality, health interventions that assist people in realizing their greatest possible state of health.

APPROACHES TO IMPROVING VALUE: COVERAGE AND REIMBURSEMENT

Steven D. Pearson, M.D., M.Sc., Institute for Clinical and Economic Review

The sequel to Philip Pullman's book *The Golden Compass* was entitled *The Subtle Knife*. The subtle knife was a knife so sharp that it could find the tiniest crevices in the fabric of the universe and slice openings to serve as passages between different worlds. Its ability to distinguish minute differences in space and time was beyond human understanding. Its precision was absolute (Pullman, 1997).

Coverage

No one, certainly, would argue that coverage policy is a subtle knife. Coverage policies made by public and private insurers cannot be designed to distinguish minor differences between individual clinicians and individual patients; rather, coverage policies are generated for populations. Interventions are judged upon their known effects for populations of patients. Historically—and legally—the dividing line between covered and non-covered interventions for private insurers is usually determined by whether interventions are deemed "medically necessary." Any further definition of this dividing line commonly includes requirements for interventions to fall within generally accepted standards of medical practice, to be clinically appropriate in terms of type and frequency, and to not be primarily for the convenience of the patient. Even the sum of these criteria provides a relatively weak tool for achieving improved value in the healthcare system. Under these terms, frankly "quack" treatments can be denied coverage, as can wildly "inappropriate" interventions such as month-long hospital stays to reduce weight through monitored diets. But what about fine-tuning of the use of costly interventions with questionable risk-benefit ratios? Or encouraging the use of less expensive and less invasive treatment or diagnostic options that offer comparable net benefits? Coverage by itself cannot hope to advance these value goals.

Public insurers face the same problems. Coverage within the Medicare system is guided by its own statutory language requiring that payments not be made for interventions that are not

"reasonable and necessary" (double negative in the original). Despite more than 50 years of experience, Medicare's "reasonable and necessary" dividing line for coverage has proven an even blunter tool for improving value than the "medically necessary" language of private payers. Over the years there have been periodic attempts to define the boundaries of "reasonable and necessary" in a more rigorous and transparent fashion. CMS has scheduled hearings and offered draft language to give the term "reasonable and necessary" a stronger basis. Yet each time an effort has been launched, healthcare interests have found reason to push back against what they view will be tighter restrictions on coverage. Until recent years, in fact, it has been felt by most that the history of Medicare's coverage decisions implies that strong evidence of harm is required before coverage will be denied. Denial of coverage has rarely been used when evidence of benefit over other options is lacking or even when evidence of any benefit is lacking; the default has been to provide coverage unless there is fairly clear and incontrovertible evidence of harm for most patients—a blunt knife, indeed.

However, there are ways for coverage policies to be designed and implemented in order to be more powerful tools for improving value. Some private health insurance contracts include a clause to the effect that services may not be considered medically necessary if they are more costly than an alternative service or sequence of services that is at least as likely to produce equivalent therapeutic or diagnostic results. Medicare has a similar regulation that allows it, in limited circumstances, to cover only the "least costly alternative" for durable medical equipment and injectable drugs.

Although this basic concept sounds like a potentially powerful tool to improve value, in practice it is seldom used. When used by private insurers, it is very rarely employed to deny coverage for a specific service; instead, the term is used to deny coverage for a service that is used at a higher frequency or intensity than considered appropriate. For example, a payer may deny coverage for injections provided weekly when monthly injections suffice. At Medicare, even limited use of the "least costly alternative" policy hit a major roadblock recently when a court ruled that Medicare's statutory language did not in fact allow its application in the consideration of medication coverage. Therefore, although many have hoped that better value could be achieved through limiting coverage to less costly but comparable options, the practical and legal challenges have blunted the actual impact.

Reimbursement

If coverage has proven to be a blunt knife, what are the chances that reimbursement policy can prove more effective? It is easy to assume that private payers could negotiate their own reimbursement rates, paying more for high-value services and less for low-value services. Yet payers often have broad contracts with providers that outline reimbursements rates based on Medicare rates plus or minus 5 to 10 percent. This policy makes Medicare the 800-pound gorilla in reimbursement. As a result, payers' and providers' "value" discussions are dominated by the coding and relative value units (RVUs) used to determine Medicare reimbursement. The basic premise that Medicare "reimburses" according to a formula based on physicians' time, the complexity of the service, and the cost of any material involved makes it clear that reimbursement is divorced from any consideration of the degree of clinical benefit produced by the intervention.

Highlights of Policies from Public and Private Payers

Public Payers

Medicare Medicare is eagerly employing coverage with evidence development (CED) as a reimbursement tool. CED refers to the linkage of Medicare coverage of specific, promising technologies to a requirement that patients participate in a registry or clinical trial. In recent years this approach has been applied by CMS to the coverage of several biologics approved for

colorectal cancer, implantable cardioverter defibrillators for prevention of sudden cardiac death, and positron emission tomography for patients with malignancies. The policy was framed as having a dual purpose: (1) to ensure at the time of service that the care met the Medicare standard of reasonable and necessary and, most notably, (2) to provide the basis for longitudinal data collection that would ultimately assist doctors and patients in better understanding the risks, benefits, and costs of alternative diagnostic and treatment options.

Yet CED has proven challenging to use. There remains uncertainty about whether CED is meant to expedite diffusion of services while gathering evidence about the service or whether it is simply an auxiliary stipulation beyond standard evidence requirements. This uncertainty hinders rather than helps. However, CED continues to evolve and will likely play an even greater role in the future.

Medicare also has tried to reap improved value by bundling Healthcare Common Procedure Coding System (HCPCS) payment codes to allow blended payment rates. If two HCPCS codes are determined by Medicare to be essentially identical even though they have significantly different prices, Medicare can pay a blended rate for both of the codes. A blended payment rate gives greater incentive for providers to utilize the lower-priced option because its lower base cost to the provider will mean a higher marginal profit from the payment. Blended payment is not based on the same regulation as the "least costly alternative" approach, but it serves much the same purpose: using the coverage and payment system to favor lower-priced options that have the same clinical performance.

The most recent coverage innovation developed by Medicare to foster value is its approach to denying coverage for "never events"—adverse events such as postoperative infections and blood clots that are judged to be fully preventable. Although this mechanism by itself is unlikely to produce significant cost savings in the short term, it serves as a reminder that Medicare views itself on a path toward becoming a strategic value-based purchaser of services. Through nonpayment for "never events," Medicare is progressing on the road to paying for outcomes, not just services. Great advances in value are likely as Medicare continues down this path.

State governments The states also play important roles in seeking new ways to use coverage and reimbursement to promote value. One example is Washington State, which passed legislation creating a Health Care Authority (HCA) responsible for performing health technology assessment to guide coverage decisions. The Washington HCA has an 11-member panel that makes coverage decisions for all of the state's public programs on the transparent basis of safety, efficacy, and cost-effectiveness. In the face of limited resources, the program's mandate is to increase value for the state's healthcare dollars.

Consider its decision regarding computed tomographic colonography (CTC), which is a screening test for colorectal cancer. The HTA commissioned the Institute for Clinical and Economic Review (ICER) at Massachusetts General Hospital to conduct an evidence review for CTC compared to traditional colonoscopy. Assessing both comparative clinical effectiveness and comparative value, ICER's evidence review concluded that CTC was clinically comparable to colonoscopy for cancer screening but likely of low value because of the higher costs and frequent need for repeat testing. Yet the review suggested that if the cost for CTC was lowered to one-third of the cost of a colonoscopy, as is the case in parts of Wisconsin, where several private insurers cover CTC, CTC could be considered to be a high-value service. In Washington State, since the reimbursement rates for CTC and colonoscopy were equivalent, the HCA decided not to cover CTC for colorectal cancer screening at that time.

Private Payers

For private payers, tiered drug formularies, prior authorization, centers of excellence, and tiered networks of hospitals and providers represent a few of the mechanisms they have developed to apply evidence through benefits design and the management of medical services to increase value. For example, through tiering—now a near-universal part of drug coverage—private payers increase out-of-pocket payments for lower-value services and drugs. Many private payers also employ what are called step programs—or step edits—in which patients with a particular condition must start with a particular (lower-cost) drug and have inadequate results with that drug before the payer will extend coverage to a second, more expensive drug.

Alongside step edits are often found physician edits, which limit the prescription of certain drugs to specific types of medical specialists who, it is assumed, are more likely to have the clinical experience to judge when a more expensive, and sometimes more dangerous, drug is appropriate for an individual patient.

Two publicly known examples of conditional coverage provide a sense of how these approaches can be used to improve value. One example involves the drug trastuzumab, also known as Herceptin, which is effective in the treatment of breast cancer only among patients who have a specific tumor marker. Herceptin can have significant side effects and is also a very expensive medication, making it important on many levels that it be used only in patients who are likely to benefit. In a study reported by UnitedHealthcare, however, approximately 20 percent of enrolled patients being treated with trastuzumab lacked the relevant tumor marker (Culliton, 2008). A considerable number of patients were receiving the drug without any hope of benefiting from it. As a result of this study, UnitedHealthcare developed a new policy requiring documentation of the tumor marker before extending coverage for the drug (Phillips, 2008).

Another example of conditional coverage involves adalimumab (Humira), a biological agent used to treat rheumatoid arthritis. Health-Partners, a not-for-profit payer in Minnesota, requires prior approval for the medication, restricts its use to rheumatologists, and sets dose limits of 40 mg every other week. Additionally, adalimumab is reserved for patients with rheumatoid arthritis who have previously tried and failed at least a three-month trial of an alternative agent. After these criteria are met and approval is provided, the drug must be obtained though a specific specialty pharmacy. Through the integrated application of physician edits, step edits, and dosage limits, payers hope to increase value by targeting this expensive medication to those patients who need it and will most likely benefit from it.

Future Considerations for Coverage and Reimbursement

The future of reimbursement and coverage among private payers may include risk-sharing arrangements, such as the adoption of population capitation arrangements. In these arrangements a payer may contract with a pharmaceutical manufacturer for a specific price to cover an entire population. The goal of this arrangement is to provide a reasonable profit to manufacturers while incentivizing them to work toward appropriate use of the drug within the population who will benefit from it. Another type of risk-sharing arrangement that may be seen in the future is one in which provisional approval for coverage is given with initial reference pricing for a new drug; the potential for price increases in the future is tied to whether future data evaluation demonstrates increased efficacy over other options. Other types of risk-sharing agreements that are likely to be considered can be drawn from the experience in the United Kingdom, where a value-based evaluation process has led to various types of agreements. In one example, a pharmaceutical company received coverage for its drug only when it agreed to reimburse the National Health Service when the medication proves to be ineffective for a patient.

The future of Medicare's ability to use coverage and reimbursement to improve value will depend on its collaboration with manufacturers and physicians. All parties should work together to determine the role evidence will play in coverage, reimbursement, and physician payments. It will

be helpful if CMS can provide clearer guidance to manufacturers and others about general guidelines for the evidence requirements needed for coverage and reimbursement determinations—for example, details regarding the recommended length of and outcomes for clinical trials. With the seeming demise of the least-costly-alternative reimbursement approach, hopefully Congress will take the opportunity to reformulate reimbursement policies in light of evidence of clinical value in order to give Medicare the tools it needs to obtain the highest value possible for every dollar spent.

State governments should continue to serve as important laboratories for using evidence in coverage and reimbursement in ways that advance value. They may benefit from collaboration in the commissioning of evidence reviews and can share their lessons learned in translating evidence into coverage and reimbursement to help guide states just starting out on this path.

Finally, all stakeholders will benefit from an enhanced national commitment to comparative effectiveness research. A comparative effectiveness initiative that produces and effectively disseminates authoritative evidence on clinical and cost-effectiveness will help patients and clinicians make more "value-oriented" decisions on a day-to-day basis. Better evidence will also support innovative coverage and reimbursement policy that can align all interests in providing higher value. Coverage and reimbursement are relatively blunt knives, but there are many ways to control costs that are more subtle. With transparent links to good evidence, coverage and reimbursement have great potential to help patients and the United States achieve a high-quality, sustainable healthcare system.

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