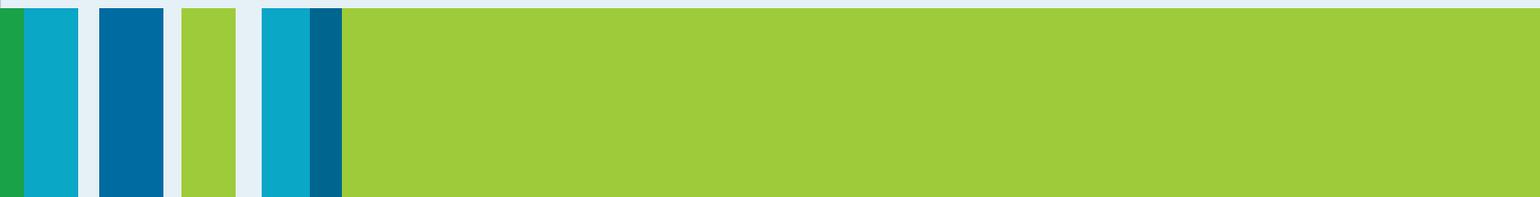


PAYING FOR PERSONALIZED MEDICINE

How Alternative Payment Models
Could Help Or Hinder The Field

EXECUTIVE SUMMARY



PAYING FOR PERSONALIZED MEDICINE: HOW ALTERNATIVE PAYMENT MODELS COULD HELP OR HINDER THE FIELD

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At a time of unprecedented scientific and medical breakthroughs, personalized medicine has the capacity to more accurately diagnose human diseases, predict individual susceptibility to disease based on genetic or molecular factors, detect the onset of disease at early stages, pre-empt its progression, target treatments, and increase the overall efficiency and effectiveness of the health care system. This progress has brought us major treatment advances that will improve patient outcomes, with the greatest impact being felt by those with serious and life-threatening conditions and unmet medical needs, like many cancer patients.

Advances in the science of personalized medicine are leading to important advances in the diagnosis and treatment of cancer and many other serious and life-threatening diseases. As stated in one recent article by leaders from the field of oncology, “With continued support for science and innovation, we foresee accomplishing in oncology what has been achieved against other major public health problems, such as HIV/AIDS, in which scientific advances yielded major gains for patients and averted a predicted health spending crisis.”¹

The emergence of personalized medicine is eliciting growing excitement and optimism among patients, providers and policymakers as a new wave of targeted therapies emerges and demonstrates the potential of the field to improve patient outcomes and health care delivery. At the same time,

growing demands for health care cost containment are driving increased interest in “alternative payment models” (APMs), as policymakers seek approaches that can balance care quality, cost containment, and physician-patient decision-making autonomy.

Policymakers in Congress and the Administration have been at the forefront of both these trends. On January 26, 2015, Secretary of Health and Human Services (HHS) Sylvia M. Burwell announced a goal of tying 50 percent of traditional, or fee-for-service, Medicare payments to quality or value through APMs by the end of 2018. In an effort to lower costs for the Medicare program, HHS set explicit goals for transitioning health care services for the Medicare beneficiaries to APMs and value-based payments.

Similarly, both Congress and the Administration have proposed initiatives to accelerate development of personalized or precision medicine. Sponsors of the 21st Century Cures legislation have expressed interest in including provisions directly addressing the need to better align regulatory and reimbursement policy with personalized medicine, and in January 2015 the Obama Administration announced a new Precision Medicine Initiative involving a \$215 million investment in research, and, to a lesser extent, regulation and standards. Additionally, Congress finally passed legislation replacing the much maligned “Sustainable Growth Rate” (SGR) formula with a system that is designed to incentivize physicians to participate in APMs in greater numbers to avoid future Medicare reimbursement cuts.

This white paper is being written at a critical time in the evolution of personalized medicine. Ongoing advances in personalized medicine have the potential to turn the tide against a wave of illnesses that span from cancer to Alzheimer’s, and changing market dynamics and major policy initiatives may derail or accelerate progress.

The Personalized Medicine Coalition (PMC) commissioned this paper to identify critical issues that must be addressed in order to support access to personalized medicine in a market that is moving toward paying for tests and treatments through APMs or value-based payment models.

Both private insurers and HHS continue to develop demonstration projects that test new delivery and payment models. Examples of APMs that government health care programs and private insurers are experimenting with include accountable care organizations, patient-centered medical homes, and bundled payment systems. Understanding each type of APM, and how it affects both the utilization and development of innovative treatments for complex diseases, is key to understanding the implications of APMs for personalized medicine.

In addition, many APMs will create incentives for use of care protocols, clinical pathways, and other clinical decision support tools. It will be essential to ensure that these tools reflect the state of the science and current standards of care. As personalized medicine provides new insights on the role of genetic variation in patient response to therapy, clinical pathways and other decision support tools will increasingly be challenged to keep pace.

APMs and personalized medicine both hold significant potential to contribute to better, higher-value, more individualized care. To realize this goal, it is essential that the design of APMs support personalized medicine.

This paper identifies and describes how the design of APMs might encourage the delivery of the high-quality, patient-centered care made possible by personalized medicines. Important factors that are essential to the future development of APMs include:

- The degree of transparency in their development and evaluation across all stakeholders, including patients, providers, manufacturers, and payers
- The role of informed decision-making based on genomic and other research within APMs
- The use and appropriate weighting of clinical quality measures that are focused on outcomes

- The structure of provider financial incentives that support patient choice, and
- The inclusion of mechanisms to recognize and encourage appropriate adoption of personalized medicines.

The Personalized Medicine Coalition would like to thank Andrew Shin JD, MPH, ML Strategies, the principal author of this report, as well as those of our members who took the time to read and comment on this paper's many drafts.

1 A. Abernethy, E. Abrahams, A. Barker, et al. "Turning the Tide Against Cancer Through Sustained Medical Innovation: The Pathway to Progress." *Clinical Cancer Research*. February 2014.

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A CRITICAL TIME FOR INNOVATION

Personalized medicine is revolutionizing health care as we know it. Personalized medicine is an emerging field that uses diagnostic tools to identify specific biological markers, often genetic, to help determine which medical treatments and procedures will be best for each patient. Through collaboration with an individual's medical records and circumstances, doctors and patients are able to develop targeted prevention and treatment plans.

Recent advances in genomic technology have significantly decreased genetic sequencing costs. Together with increases in computing power and information management tools, these technologies are accelerating the advancement of disease biology, the creation of novel and complex diagnostics, and the development of molecularly targeted therapies. Patients have already benefited from major biological insights and medical advances, including the development of more than 100 drugs with labels that include pharmacogenomic information.¹

These specially tailored treatments can greatly improve survival chances.² Additionally, consideration of an individual's pharmacogenomic profile in prescribing can find the most effective treatment dose more quickly while avoiding adverse drug reactions, increase patient adherence to treatment, improve quality of life, and reduce trial-and-error prescribing. Overall, personalized medicine can help control the cost of health care and shift medicine's emphasis from reactive to preventive.³

We are at a critical time in the evolution of personalized medicine. Pharmaceutical company research and development pipelines are rapidly shifting toward more accurate diagnoses and effective treatments that represent breakthroughs in clinical innovation. Scientists, clinicians, patients, and increasingly, policymakers are beginning to recognize the transformative potential of personalized medicine, and are seeking ways to accelerate its development and adoption. For example, President Obama recently announced a Precision Medicine Initiative that recognizes the benefits of "treatment that takes into account individual difference in people's genes, environments and lifestyles."⁴

However, the regulatory and financial systems that will support these innovations are not yet in place. Laying the foundation to support personalized medicine will not only improve patient outcomes and control health care costs, but also introduce new scientific, business, and medical models. Therefore, this white paper aims to identify critical issues that must be addressed in order to support access to personalized medicine in a market that is increasingly paying for these tests and treatments through "value-based" or "alternative" payment models like Accountable Care Organizations (ACOs), bundled payments, and clinical pathways.

A Time for Transformation and Innovation

In 2010, Congress passed the Patient Protection and Affordable Care Act together with the Health Care and Education Reconciliation Act of 2010, known collectively as the “Affordable Care Act” (ACA). The new law transformed the U.S. health care system through an expansion of coverage through tax subsidies, regulated marketplaces, and publically financed government health programs.

In addition to the many reforms that changed health insurance, the ACA focused on improving the quality of our public health and health care delivery systems, while also identifying ways to reverse the trend of medical spending that ranks U.S. expenditures at a higher rate, both per person and as a percentage of GDP, than any other industrialized nation in the world.

Until recently, the vast majority of initiatives designed to lower the growth rate in health spending have been targeted at replacing or adding incentives on top of the fee-for-service (FFS) system, even while FFS is often cited as the root cause of systemic misaligned incentives that reward volume over value.⁵ The main criticism of the FFS system stems from its failure to provide meaningful incentives for efficiency, quality, or outcomes. Put another way, the system often discourages coordination of care and management of patients across different providers and settings along the care continuum.

Yet, amidst the narrative of increasing interest in controlling health care spending, the scientific community is on the cusp of a new era in clinical innovation, ready to usher in the age of personalized medicine. Structuring care payment and delivery systems to recognize and support the value of personalized medicine will be essential in ensuring that patients can access it and that investors are willing to fund its development.

New diagnostic tools have allowed for more targeted use of some drugs that have been used in clinical practice for years, a trend that is likely to intensify as clinicians and scientists further mine new opportunities to tailor therapies for the individual. Further, targeted therapies have helped to reduce ineffective medication use, thereby improving outcomes and lowering overall spending. All of this benefits clinical practice and patients and should produce long-term cost savings in the health care system.

As a result, it becomes essential for health care stakeholders and policymakers to better understand the underpinnings of personalized medicine, how it is changing patient care, and how payment policy reforms can better align with and support the value of this new field.

The Proliferation of Alternative Payment Models

One way the ACA has acted as a catalyst in pushing health care towards value-based payment systems was by granting new authorities to the government agencies that oversee the federal health care programs. For example, the Centers for Medicare and Medicaid Services (CMS) have developed dozens of demonstration projects that test new delivery and payment models, hoping to eventually replace the current FFS model with one or more alternative payment models (APMs).

In early 2015, the Obama Administration made a sweeping announcement to achieve the goal of tying 30 percent of FFS Medicare payments to quality or value through APMs by the end of 2016, and tying 50 percent of payments to these models by the end of 2018. Concurrently, policymakers in Congress have also introduced a number of high-profile proposals over the past five years, many of which were bipartisan, that cover the spectrum of models from bundled payment approaches for particular chronic diseases to additional authority for the government to implement new APMs.

The recent popularity of APMs is due to the fact that, if done well, they present a new set of incentives in the health system that could improve care coordination and outcomes while controlling costs. However, if structured inappropriately and without the necessary safeguards to ensure high quality care, APMs could lead to unintended consequences that could limit access to vital services and medicines.

In the private sector, commercial health plans, employers, and other payers have also lauded the potential for APMs to change provider behavior for the betterment of patients in both the quality of care they receive and associated costs.

During the debate of the ACA, employer groups in particular focused on how APMs should be an essential part of national health reform. As the Pacific Business Group on Health, a coalition of public and private purchasers of health care, stated in its testimony before the Senate Finance Committee, “We must design payment systems to reward providers for giving the right care at the right time and encourage patients to be actively engaged in their care.”⁶

The concept of “right care at the right time” has been a central theme in designing APMs that have included most prominently:

- *Accountable Care Organizations (ACOs)* that utilize shared savings incentives for an attributed population;
- *Episode-Based Payments* (also known as “bundled payments”) that pay for a set of services for a specific condition or procedure; and
- *Medical Homes*, which focus on care coordination, usually via a primary care practice.⁷

Tools such as *Clinical Pathways and Transparency* have also been used to assist providers participating in APMs, or in some cases, have been used alone.

Although the most popular APM initiatives differ in significant ways, for the most part, providers have significant leadership roles in steering the models. In the capitation methods of the 1990s, payment systems excluded certain providers from networks and rewarded them almost solely on cost alone without any regard to health outcomes.⁸ Success in a contemporary value-based environment depends upon providers managing both economic and quality elements and successfully incorporating patients into the decision-making process.

Yet, similar to the concern that expanded coverage via the ACA could exacerbate existing weaknesses in the U.S. health care system is the concern that as APMs grow in scope and scale, so will the inherent biases embedded in a payment system that has, in large part, operated with indifference to patient-centered value and quality. Because APMs are likely to factor as large parts of any plan to improve the sustainability and quality of the U.S. health system, policymakers and stakeholders are likely to confront a crossroads between changing payment systems and rapidly evolving clinical innovation through personalized medicine.

Successfully navigating this challenge will require policymakers to design new payment models that aim to reduce near-term spending but continue to support ground-breaking innovation that could dramatically improve the quality of care and lower costs in the long term.

THE PROMISE OF DELIVERY SYSTEM REFORM AND THE EVOLVING ROLE OF PERSONALIZED MEDICINE

As APMs continue to evolve, policymakers must negotiate a delicate balance between reducing health care costs and delivering high quality care that simultaneously preserves patient choice. At the same time, personalized medicine and other advances are creating opportunities to change the treatment paradigm for some of the most lethal and debilitating diseases spanning cancer to HIV/AIDS. Personalized medicines, in particular, have already begun to change the narrative from *reaction to prevention* and *treatment to cure*.

In an era in which targeted therapies and companion diagnostics can detect the onset of disease at its earliest stages and pre-empt the progression of disease far beyond the current diagnosis and treatment paradigm, the central question becomes: *How do we develop a payment system that recognizes the potential of personalized medicines, ensures patient access, and rewards continued innovation?*

Further complicating the landscape is the reality that targeted products are not necessarily optimally personalized at the time they are first approved. The current clinical trial process provides a scientific basis to approve therapies, but their ultimate impact, especially for certain subsets of a particular population, may not be available to clinicians for some time following approval. Continued research and experimentation with the use of these products will ultimately identify additional indications and refine the patient subsets that stand to benefit from them. The question then becomes: *How should the system be designed to recognize the incremental value of these personalized therapies as more information becomes available as to their effectiveness?*

Indeed, in creating new systems and processes, personalized medicines do not often correspond to how we currently define and measure quality using today's concept of value. The very nature of these targeted therapies requires completely different mechanisms to:

- 1) Empower clinicians with the tools they need to provide the highest quality care possible; and,
- 2) Facilitate engagement around data and quality between health care stakeholders.

Although personalized medicines represent some of the greatest breakthroughs in clinical science to-date, the way our health system measures and rewards that value is highly variable. Many of these new technologies are at the cutting edge of scientific discovery and represent substantial resources in terms of research and development in order to come to market. Thus, the remainder of this white paper will discuss important issues that policymakers should consider as they continue to develop these new payment models and work to transform health care payment while appropriately leveraging personalized medicines to improve quality.

Measuring Quality

At the core of maximizing value for patients and enabling providers to deliver that value is a shift in the fundamental structure of how we pay for health services. The current FFS system largely incentivizes volume over outcomes/quality. Thus, policymakers have focused a great deal of their efforts around payment reform initiatives that realign incentives with the dual goals of reducing costs and maintaining or improving quality.

Although lowering costs may be the leading impetus for many policymakers to reform the health care system, the recent proliferation of targeted therapies and advanced diagnostics has added complexity to the role quality improvement plays in realigning payment systems. The current portfolio of APMs varies greatly with respect to treatment of quality, with some APMs tying payment for an entire procedure/treatment to distinct events such as hospital readmissions or electronic medical record (EMR) utilization and others using patient-satisfaction surveys and other data to justify bonus payments.

In terms of evaluating the most popular APMs currently under implementation (ACOs, bundled payments, and medical homes), the role of personalized medicine varies greatly depending on what the payment initiative targets and how the financial incentives are determined with respect to cost and/or quality. *Thus, structuring payment systems to target the right conditions and aligning them with the right measures has become the most significant issue for policymakers hoping to enable providers to quickly redesign care.*

Quality improvement is a foundation of a patient-centered health care system. Ideally, APMs are structured to incentivize providers to offer high value care by holding providers accountable for a specific patient during a predetermined time period or over the course of a treatment. While accountability certainly includes *cost*, it also includes *quality of care*.

The Institute of Medicine defines quality as “the degree to which health care services for individuals and populations increase the likelihood of desired health outcomes and are consistent with professional knowledge.”⁹ In other words, did the patient receive the right care, at the right time, in the right place?

To properly assess quality of care, organizations that span payers, providers, academics, and government have committed significant resources to develop appropriate quality measures. In the context of APMs, quality measures serve as important benchmarks to assess the quality of care that patients receive and provide goals for providers to work towards. Quality measurement is often categorized by: *process*, *outcome*, or *efficiency* measures.

- *Process measures*: determine whether a specific health care service was provided to a patient consistent with evidence-based guidelines.
- *Outcome measures*: assess the health status of a patient after receiving health care services.
- *Efficiency measures*: evaluate the relationship between the cost of care that has been provided and the quality of that care.

Quality measurements can be collected for different purposes, including quality improvement, accountability, and/or research. In the APM context, measurements are collected for both accountability (determining payment levels) and quality improvement (is the care that is provided getting better or at least being maintained over time?).

Recently, there have been efforts to promote quality measurement that captures the value gained from interventions that improve a patient's quality of life and/or functional status. Coupled with robust outcome measurement and appropriate weighting in determining payment, quality measurement plays a vital part in determining what behavior change(s) are likely to occur within APMs. In other words, for APMs to be successful, quality measurement must be *comprehensive* and *accurate* enough to ensure every patient receives the highest quality of care, while also being appropriately *valued* as part of a payment mechanism so that providers are incentivized in a truly patient-centered manner.

Prevailing Alternative Payment Models

While there are many variations of payment models that range from payment-for-reporting to full capitation, the most prominent APMs currently implemented, especially in the Medicare program, are generally classified in three categories: ACOs, bundled payments, and medical homes. Even within these categories, there are numerous iterations of models with varying levels of participation across the country.

The following is a summary of the three most pervasive APMs and a discussion of how the balance between quality and cost-savings may affect clinical innovation in a personalized medicine context.

1. ACCOUNTABLE CARE ORGANIZATIONS (ACOS)

ACOs allow for shared governance from a variety of stakeholders through which they are able to work together to manage and coordinate care for a specified group of patients. The two main models in the Medicare program include the larger Medicare-wide program known as the Medicare Shared Savings Program (MSSP) and the smaller pilot known as the Pioneer ACOs.

In both models, providers can form legal entities with other providers and are then held accountable for cost and quality for a defined population of Medicare beneficiaries. ACOs that enter into two-sided risk arrangements are given a target spending benchmark based on the historical cost of their attributed Medicare population and can earn “shared savings” based on the amount of Medicare spending below the benchmark in a given year. Alternatively, if an ACO cannot contain costs beneath their target amount, they may be required to pay back the Medicare program.

It is important to note that the Medicare ACO programs are not the only operational ACO models. Other payers, such as Medicaid, private health plans, and even some large self-insured employers, may take a different approach to structuring their payment mechanism for ACOs.¹⁰ For example, either lower cost or higher quality could be the focus, and it could be for a limited number of conditions or a narrower population.

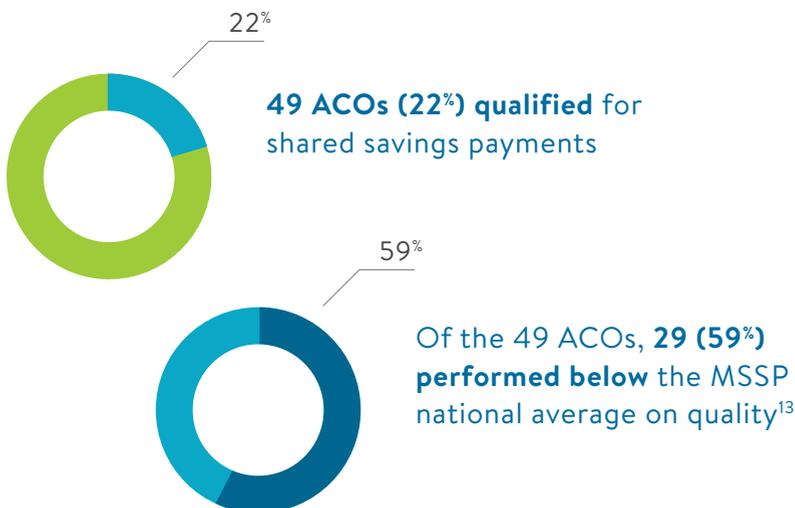
Although there are varying financial structures available to ACOs, including strictly shared savings, in which the ACO faces no downside risk for higher spending for a given population, most health policy experts believe that the ultimate goal is to eventually transition ACOs to population-based payments (a contemporary form of “full-capitation”¹¹). In this model, providers are given a set payment per patient, rather than per service. The payment would be a set dollar amount per patient, regardless of how many health care services the patient received.

While payment models that put providers at financial risk are more likely to induce ACOs to control spending and improve efficiencies, thereby lowering health care expenditures, these benefits may be outweighed by the multiple possibilities for harm to patients if the capitation model is poorly implemented. Although personalized medicines often represent the potential for significant quality improvement, depending on how quality measures are designed and payment parameters are structured, the ACO model could end up limiting access to them.

Rigorous quality measures can mitigate this potential danger to patients. However, the pressure to achieve near-term savings is likely to be even more acute in situations where the ACO is ill-prepared to bear financial risk. Depending on how well ACOs are able to redesign care and build (and properly utilize) infrastructure, this transition could represent a challenge for ACO participants as they assess where to extract cost-savings. This makes quality measurement even more important as both a safeguard for patients and a guidepost for providers as they transition towards more risk-bearing arrangements in APMs that certainly include, but are not limited to, ACOs.

Today, quality measurements in the Medicare ACO programs are structured to meet certain benchmarks. ACOs that fall below minimum quality benchmarks would not be able to share in savings, even if they are able to achieve cost savings below their spending benchmark. So far, the initial evaluation of the ACO program demonstrates that the current quality measurement structure may lack the ability to ensure full success and sustainability of the model. During September 2014, CMS released the following quality and financial performance data for MSSP ACOs that began in 2012 or 2013.¹²

CMS QUALITY AND FINANCIAL PERFORMANCE DATA FOR THE MEDICARE SHARED SAVINGS PROGRAM (MSSP)



Released September 2014

This initial evaluation of the ACO model demonstrates that ACOs do not necessarily need to *improve* quality to earn payment. Put another way, the weight of the quality measures may not have a causal effect on provider decision-making in the current ACO model. This begs the question: *What does this mean for the adoption of clinical innovations that may change the treatment paradigm in ways that are not adequately measured, such as personalized medicines?*

Ideally, by requiring ACOs to meet certain minimum quality measurements to receive payment, providers are more likely to reduce costs through reductions in waste and improved efficiencies, as opposed to skimping on necessary care. Following that logic, personalized medicines, representing extraordinary improvements in quality, should see steady utilization among providers who want to take advantage of clinical breakthroughs for their patients. Yet, the initial evaluation of ACO quality and financial performance data brings into question how much confidence we can have that the balance and composition of quality measures is enough to overcome significant financial incentives.

Further, while the data demonstrate that ACOs will inherently work to meet their savings goals with mixed quality improvement results, we can only speculate how those ACOs are performing in areas that are not being measured. In a somewhat ironic reversal, quality measure thresholds may also have an unintended consequence of diminishing providers' focus on the care that falls outside what is being measured.

While it is highly unlikely that providers would ever intentionally provide suboptimal care, it is reasonable to believe that the importance placed on meeting cost and quality benchmarks could draw the vast majority of providers' attention towards only those conditions being measured. Put another way, where new technologies such as advanced diagnostics and targeted therapies are available, without overwhelming evidence and years of adoption, there is a strong likelihood that providers in an ACO model may be hesitant to utilize those technologies.

2. BUNDLED PAYMENTS

Bundled payments have been designed as a way to encourage coordination across different providers and to promote more efficient care. Although variations of bundled payment have existed for decades,¹⁴ the emergence of personalized medicine has occurred largely outside the evolution of modern-day bundled payment models. Since passage of the ACA, bundled payments have seen a resurgence in both public and private health care programs.

A bundled payment is a single payment to providers or health care facilities (or jointly to both) for all services to treat a given condition or provide a given treatment. This could include a procedure in a hospital, the post-acute care following discharge, and a window of time afterwards. The payment can be divided among the providers across the care spectrum. Bundled payments are often cited as a pathway towards broader initiatives because their scope is limited to one episode of care for an individual patient, usually for a time period of no more than 90 days.

Providers have the ability to redesign care for a particular set of services that better coordinate between different specialties and across care settings. Similar to the payment mechanism in ACOs, if the costs of care during the episode or timeframe are less than the bundled payment amount, the providers keep the difference. Conversely, if costs exceed payment, providers are accountable for the loss.

Crucial aspects of any bundled payment methodology include what services are included within a bundle, whether any services for an episode of care could be excluded, and for what length of time. In the prominent Medicare Bundled Payment for Care Improvement (BPCI) model,¹⁵ for example, there are up to 48 distinct clinical episodes that span congestive heart failure to sepsis.¹⁶

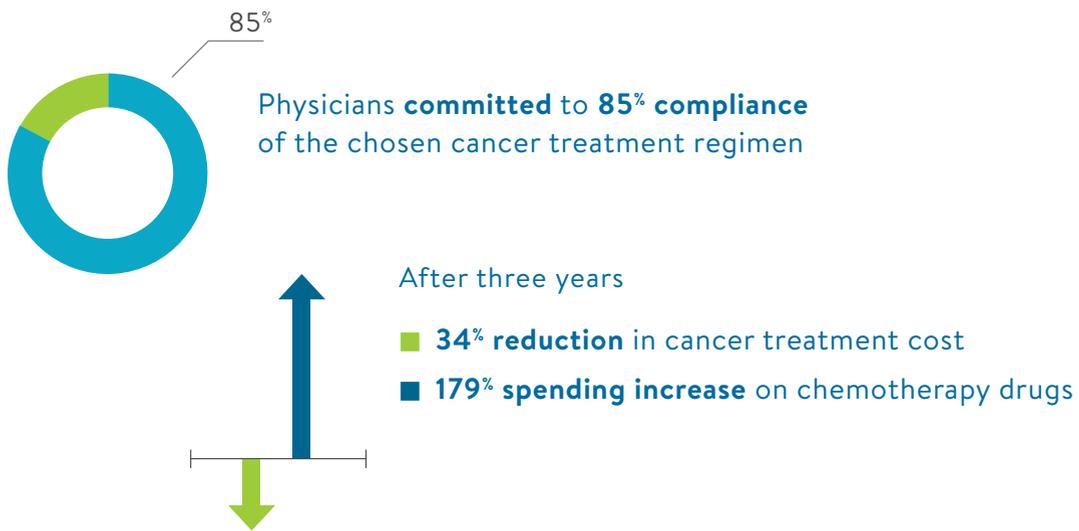
Regardless of the scope of a particular bundled payment, providers are able to achieve cost reductions and quality improvement from several factors, such as provider adherence to guidelines,¹⁷ elimination of waste and utilization reduction,¹⁸ and physician-hospital alignment. However, it is still unclear which of these factors has the greatest impact on cost reduction and quality improvement.

For the most part, therapies and diagnostics have been largely excluded from bundled payment initiatives, with the notable exception of the end-stage renal disease bundled payment program in Medicare. However, in the oncology space, where personalized medicines currently have the greatest applicability, some pilots have begun to test models that have yielded unexpected results.

In 2009, the largest commercial insurer in the country, UnitedHealthcare (United), launched a pilot program with the primary goal of reducing the overall medical costs of cancer care. The premise for the pilot was that by removing the economic incentive for oncologists to prescribe higher-cost chemotherapy drugs, overall spending would be reduced for patients being treated for cancer.

Oncology providers in the pilot program were responsible for choosing the treatment regimen they wished to use (e.g., a certain drug at a certain dose, additional drugs for side effects) for 19 specific cancer scenarios. In essence, the United pilot program put into question the causal link between drug utilization and overall health costs. The program's outcomes are presented below.

THE OUTCOMES OF UNITEDHEALTHCARE'S PILOT PROGRAM



Approximately **\$40,000** was **saved per chemotherapy patient** despite spending more on chemotherapy drugs

Whether the cost reductions came from case management services, evidence-based protocols that reduced complications/hospital admissions, or the use of innovative patient engagement tools, the results from the United pilot have only further muddied the waters when considering broader bundled payment models that include pharmaceutical therapies. The lack of understanding as to the relationship between spending on services and cost savings in APMs merits further analysis, particularly in fully understanding the effects on quality of care and short-and long-term patient outcomes.

While CMS has spent the majority of its resources on bundled payment options for acute and post-acute care through BPCI, it also released an episode-based payment for oncology in February 2015.¹⁹ The new initiative, called the Oncology Care Model (OCM), aims to deliver improved health outcomes at a lower cost by focusing on care coordination, access to care, and delivery of appropriate care. OCM's basic structure is an episode-based payment for six months, following the start of a patient's treatment with chemotherapy. The episodes include all Medicare A and B services and certain Part D expenditures that Medicare beneficiaries receive during the episode period.

As will be discussed in more detail below, OCM highlights the role of clinical guidelines within APMs, especially when concerning personalized medicines. While the OCM initiative asks providers to follow National Comprehensive Cancer Network (NCCN) or American Society of Clinical Oncology (ASCO) guidelines, the role of personalized medicine is largely absent in the model's structure. Current clinical guidelines do not usually account for patients' unique characteristics and preferences and are largely one-size-fits-all. Further, quality measures that could help broaden access to personalized medicine, such as a requirement to submit data to registries that would expand the evidence base for a particular therapy, are absent.

While models such as the OCM initiative represent steps towards more comprehensive and efficient care in cancer, the danger in the latest iterations of these bundled payments is that personalized medicines are no longer insulated as changing incentives drive provider behavior towards simply lower cost pathways. Even beyond cancer, many providers believe that the vast majority of health conditions have not yet been successfully integrated into episode-based payment models.

As policymakers consider future bundled payment models, it will become even more important to understand what resources providers need to properly assess quality and cost. Further, implementing broader bundled payments is complicated by the fact that treatments are constantly developing and changing, which is difficult when integrating less flexible mechanisms like clinical protocols. Treatments that are standard now may be quite different in a year's time, especially as personalized medicines continue to proliferate and clinicians optimize existing treatments, as in the United oncology model.

For many stakeholders, the concerns echo those in the ACO model, where cost and quality benchmarks could draw the vast majority of providers' attention towards only those conditions being measured and pressure providers away from utilizing newer treatments. The principal notion of “picking and choosing” what providers should be accountable for (and what they are not accountable for), remains a treacherous exercise.

In setting parameters and benchmarks for care today to determine incentives in the future, we may be institutionalizing a certain level of quality. In other words, in trying to create a more patient-centered health care system, locking in a payment model that is a one-size-fits-all paradigm could have stifling effects on the development and delivery of innovative treatments that represent significant leaps in quality.

3. MEDICAL HOMES

Also known as the patient-centered medical home (PCMH), this model is designed around a particular patient's needs and aims to improve access to care (e.g., through extended office hours and remote accessibility of medical records), increase care coordination, and enhance overall quality, while simultaneously reducing costs (see below).

ACCORDING TO AHRQ, THE MEDICAL HOME INCLUDES FIVE FUNCTIONS AND ATTRIBUTES:

1. Comprehensive Care

The PCMH is accountable for meeting the large majority of each patient's physical and mental health care needs, including prevention and wellness, acute care, and chronic care requiring a team of providers.

2. Patient-Centered

The PCMH actively supports patients in learning to manage and organize their own care at the level the patient chooses.

3. Coordinated Care

The PCMH coordinates care across all elements of the broader health care system, including specialty care, hospitals, home, and community services.

4. Accessible Services

The PCMH delivers services to patients quickly through both in-office and remote mechanisms, including 24-7 access to a member of the care team and alternative methods of communication such as email and telephone care.

5. Quality and Safety

The PCMH demonstrates a commitment to quality through ongoing engagement in best practices, performance measurement and improvement, and responses to patient experiences and patient satisfaction.

Adopted from AHRQ Patient Centered Medical Home Resource Center

Whereas ACOs are focused on populations, and bundled payments on episodes of care for a specific condition or procedure, medical homes are usually focused on an individual patient. The medical home relies on a team of providers, such as physicians, nurses, nutritionists, pharmacists, and social workers, to help manage a patient's care.

According to the Agency for Healthcare Research and Quality (AHRQ), a PCMH is defined “not simply as a place but as a model of the organization of primary care that delivers the core functions of primary health care.”²⁰ Not all medical homes look alike or use the same strategies to reduce costs, improve quality, and coordinate care.

While the role of personalized medicines within medical home settings is still evolving, oncology care provides us with the best example of how this APM could help personalize care. The Patient-Centered Oncology Medical Home (PCOMH) model includes a fixed, per-member per-month (PMPM) care management fee on top of the normal FFS payment. This fee can be used to support services not reimbursed through FFS or for infrastructure investments.

The initiation of the payment model begins with a patient's diagnosis, when the practice assumes primary responsibility for the coordination of all services related to the cancer and coordination with other providers for any non-oncologic care, extending through to the survivorship phase. The most well-known PCOMH is pioneered by Dr. John Sprandio through his Consultants in Medical Oncology and Hematology (CMOH) model. Early results showed that emergency department visits at the practice fell by 68 percent, hospital admissions for chemotherapy patients fell by 51 percent, and length of stay fell by 21 percent.²¹

These reductions were driven through promotion of care standardization and cost-effective symptom management. Despite signals that quality of care has improved, Sprandio

has suggested that without payer support,²² the model is economically unsustainable under the current FFS system.

Although medical homes are much more focused on case management and access to primary care, they are also likely to have at least a modest impact on the utilization of personalized medicine, especially when considering the role of diagnostics and that the primary care physician is the gatekeeper under many health plans.

4. CLINICAL PATHWAYS AND TRANSPARENCY

Whether independent or as embedded tools in an APM, clinical pathways are becoming more common every day. For drugs and diagnostics, pathways may incentivize physicians to choose one therapy over another solely based on its availability on a particular pathway that is instituted by a patient's insurance coverage. For pathways to be accepted by the medical community, it is important to understand what incentives and data a payer uses to choose one pathway over another. Typically, preference for a particular pathway is based on evidence-based research, and for pathways to support personalized medicine, that evidence base must be updated regularly.

The availability of evidence-based research depends in large part on how a particular entity defines "evidence-based" research. As observational data and non-experimental research designs become increasingly common via expanded electronic databases, the threshold for making payment decisions within a class of drugs becomes even more problematic, even as the proliferation of personalized medicines continues.

For example, in the old paradigm, several manufacturers would make a product in a particular class of drugs for a particular condition. Based on whatever information was available, a physician may make a recommendation on one of those particular drugs. With personalized medicines, only patients with a particular genetic profile might be in the target population for one particular therapy, and the subset of patients who qualify for a particular therapy may change over time as clinical evidence becomes available.

Today, APMs can include "pathway adherence" as one component of their care redesign, while some initiatives have stricter requirements for compliance with clinical pathways. Some preliminary findings from pilot studies of clinical pathways suggest the initiatives have slowed cost growth, reduced the frequency of unnecessarily aggressive treatments, and avoided making outcomes worse. One study of a cohort of lung cancer patients showed a 37 percent reduction in drug costs over the course of the 12-month study. However, a majority of these savings were associated with adjuvant and first-line chemotherapy drugs, with no cost savings found in second-line settings.²³

More conservative cost-reduction estimates were recently announced by WellPoint, Inc., one of the nation's largest health plans, which launched a clinical pathways payment program

in July 2014.²⁴ The program provides a \$350 PMPM payment for each cancer patient treated through specific recommended pathways. WellPoint estimates that the new program will reduce treatment costs by between 3 percent and 4 percent annually.

Though many clinical pathway studies have focused extensively on the cost savings they are able to generate, little research has been done to determine whether these approaches benefit patients in terms of their short- and long-term outcomes. Pathways primarily result in a one-time savings after implementation, but there is the potential that continuing their widespread use could constrain the ability of patients and providers to choose from the most recent and broadest range of available treatment options. Further, because they are generally developed based on the broader population, pathways risk missing opportunities to tailor treatment based on an individual patient's diagnostic information and life choices.

Clinical pathways are also developed using varying levels of evidence-based medicine and stakeholder collaboration, making some pathways less flexible for providers who want to offer personalized medicines to their patients. Finally, because the level of evidence needed to justify the utilization of a particular personalized medicine is likely to take more time and require additional information infrastructure, it becomes essential for payers to work with personalized medicine stakeholders early on to structure pathways appropriately.

Thus, the key for policymakers as they increase their reliance on clinical pathways as part of APMs is to consider: in what manner the pathways were developed, why (a) specific pathway(s) was/were chosen for a particular APM, and the ability of patients to access care that is unique to their individual needs and characteristics — all while accounting for the rapidly evolving information cache for specific personalized medicines.

Finally, *transparency* has also continued to gain traction as an essential element of APM development, and is sometimes an end-goal in and of itself. Although transparency is often a necessary and laudable goal, transparency without recognizing critical data gaps could be damaging in a personalized medicine context. For example, reporting specific genetic information or other biomarkers could illuminate why a particular therapy is the most appropriate treatment. Including information on life decisions could also help add specificity to transparency data and help mitigate the risk of unfairly characterizing spending and utilization where, for much of the population, a course of treatment would not be appropriate.

In the case of clinical pathways and transparency, the core issue remains that, as the science of health care shifts to an individual patient's unique needs and biology, our payment and measurement systems must adapt.

Balancing Quality and Cost

1. LIMITING PROVIDER FLEXIBILITY AND PATIENT CHOICE

Personalized medicines may represent life-altering improvements; however, the incentive to make them available to patients is lacking when providers are evaluated on, or worse, penalized for, health spending that may yield improvements not even contemplated in a specific window of time.

In their June 2014 report, the Medicare Payment Advisory Commission (MedPAC), the independent group of health policy experts that advises Congress, stated their concerns about the flawed nature of Medicare's current quality measurement approach:

- *It relies on too many clinical process measures that, at best, are weakly correlated with health outcomes and that reinforce undesirable payment incentives in FFS Medicare to increase volume of services.*
- *It creates an incentive for providers to focus resources on the exact care processes being measured, whether or not those processes address the most pressing quality concerns for that provider...²⁵*

They went on to say that “Medicare’s quality measurement systems seem to be increasingly incompatible with the Commission’s goal of promoting clinically appropriate, coordinated, and patient-centered care at a cost that is affordable to the program and beneficiaries.”²⁶

The MedPAC report highlights a central problem with how many APMs are currently structured: the paradigm of *saving money* in a specific *period of time* may be appropriate for services and procedures that have been relatively unchanged for years (if not decades) but not necessarily for new technologies, especially for therapies that dramatically improve the quality of life for individuals over the course of many years.

Thus, the danger for providers is that the current structure of an APM may require them to find cost reductions in areas where they lack enough experience and data to fully understand the effects of their actions. For example, in a recent survey, 93 percent of ACOs reported serious deficiencies in readiness to quantify cost offsets and demonstrate the value of appropriate medication use.²⁷

In the popular MSSP model, ACOs are evaluated on clinical outcomes for conditions such as heart failure and diabetes, yet similar quality metrics are not in place for conditions that often

require more costly specialty drug use (e.g., rheumatoid arthritis, multiple sclerosis, hepatitis C). In these circumstances, ACOs may have incentives to pursue cost reductions without monitoring corresponding quality indicators to ensure optimal care.

In the case of bundled payments, which use historical spending to set a target price (usually a few percentage points less than the average cost of a particular procedure/condition over the last several years), the necessary skills and services furnished are likely to have been established over a long period of time. Further, the measures that bundled payments use to establish “quality” are often tied to interventions under the control of a physician or hospital, such as readmissions within 30 days or hospital-acquired infections.

By using historical cost and best practices as the benchmarks to establish value, contemporary APMs may also be unable to adequately account for new therapies that may treat an unmet need. For example, a particular drug therapy may not yet be widely available when a bundled payment amount and quality measures are established. Further, for personalized medicines in particular, the effect on health care outcomes for specific subpopulations may not yet be fully understood during the historical benchmarking time period.

In the other direction, bundled payments rarely contemplate costs that are beyond a 30- or 90-day window. In determining the value for a therapy that significantly reduces the recurrence of cancer, for example, the cost savings of avoiding future hospitalizations and treatments may be many years later, and thus beyond the period of time that bundled payments can currently capture. Personalized medicines that represent a change in the treatment paradigm, which many do, are ill-suited to be measured within such a narrow timeframe.

Ultimately, by designing APMs to achieve certain spending targets based on historical cost, employing quality measures that are not focused on both short- and long-term outcomes, and limiting measurement to a specific timeframe, the health care system may place serious constraints on the abilities of providers to utilize personalized medicines as they become more widely available. For patients, many of whom are not even aware that they may be receiving care within an APM, their choices may be similarly limited when incentives are solely based on historical treatments and outcomes.

2. SOCIETAL NEED

From a societal perspective, personalized medicines present the opportunity to significantly change the treatment dynamic for many diseases; but as with all new therapeutic modalities, there are also risks for failure.

Some patients respond with previously unimaginable results, while others respond initially, but then a series of events leads to a resurgence of disease. Perhaps most disheartening, a certain number of patients don't respond at all — even though they have been identified through diagnostic testing as appropriate for therapy. These differences are most likely owed to the tremendous diversity of genetic mutations and the complexity of human responses to therapy. As the science behind personalized medicine continues to evolve, society is served not only by the seemingly miraculous benefits for some patient populations, but also by the treasure trove of data and evidence that informs future innovations. Allowing for this process to unfold is essential to clinical discovery.

This is why it is vitally important for targeted therapies to be used in as many appropriately identified patients as possible. Without full utilization of novel therapies and a robust investigation of “why therapies work or don't work,” the massive combined investment of government, academic, and biopharmaceutical resources will not yield dividends. To reap the benefits of medical innovation that can come from personalized medicines, the APMs of today and other derivative models in the future will need to take into account the unique nature of these novel therapies and the needs of society at-large.

As our understanding of the human genome continues to rapidly grow, so does the litany of options and tools to aid providers in diagnosis and treatment. For example, oncology clinical practice guidelines currently recommend more than 30 tumor biomarkers across all cancers to aid treatment selection, with the list of potential biomarkers growing and changing in response to the rapid pace of clinical research.²⁸

3. IMPROVING OUR UNDERSTANDING OF VALUE

In 2015, ACOs participating in MSSP will see a change in quality measures that will start to shift them towards a focus on outcomes as opposed to processes. The ACOs must report on these quality measures and reach a certain threshold of performance in order to share fully in any savings they produce for CMS. Among the other measures being proposed for inclusion is stewardship of patient resources using the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey.

Although MSSP seems to be headed towards more outcome measurement that is tied to payment, the issue then becomes whether the providers have enough data to fully understand the effect certain tools will have on those outcomes. Indeed, the greatest barrier in determining

the true value of personalized medicines may be the lack of pharmacoeconomic data needed to create an evidence base of benefits versus costs.

The current FDA approval process does not require the kind of data that would yield enough information for payers to determine value, and to do so would be costly and likely delay the availability of innovative therapies. As policymakers consider expanding the scope of APMs, they should consider the time to determine value after a drug enters the marketplace.

For example, in a 2010 paper, the AHRQ conducted a meta-analysis comparing second-generation antidepressants (SGADs) to each other on efficacy and safety. It was only after 10 years on the market that the analysis was able to determine which SGADs were more efficacious because of higher tolerability, fewer side effects, and greater adherence.²⁹

In response to the need for more data demonstrating improved outcomes through the use of genetic profiling and targeted therapies, a series of studies, including randomized controlled trials, are currently underway.³⁰ Returning to oncology as an example, the millions of potential combinations that can be created among the currently available oncology drugs make it nearly impossible to assess every combination in every cancer subtype through the usual clinical trial process.

For providers participating in APMs, it becomes even more difficult to expend the resources necessary to assess the value of various personalized medicines in the face of higher costs for new technologies. Without rapid learning systems that can extract clinically meaningful information and be applied to modify clinical practice guidelines in real-time, providers are unlikely to utilize new technologies that could put their cost-savings targets in jeopardy.

One example of how a payer is attempting to create an adaptable model to counter this challenge is found in the Department of Veterans Affairs (VA) Point-of-Care Precision Oncology Program (POCOP). Utilizing electronic medical records and real-time data sharing, POCOP integrates generalized knowledge from external sources about molecular medicine in cancer with experiences of other veterans in the program, genomic information from the patient's tumor, and history with prior therapies. Ideally, POCOP could eventually serve as a model of rapid data sharing that creates an evidence base that could quickly inform treatment decisions.

Considering Personalized Medicines in Future Iterations

Although there is a growing body of research and real-world data that details the varying components and results of APMs,³¹ the impact of these initiatives on the development and accessibility of personalized medicines has yet to be fully debated in the public arena.

This white paper's publication follows recent efforts from CMS to explore expansion of APMs to cover chronic conditions and potentially include medical devices, diagnostics, and drugs. For example, on December 20, 2013, the agency's Innovation Center published the "Pioneer Request for Information"³² ("Pioneer RFI") seeking input on how to create the next generation of the Pioneer ACO program that began two years ago.

The Pioneer RFI touches on issues currently not at play for any Medicare ACO. For example, the CMS Innovation Center sought comments on whether Part D, the Medicare drug coverage program, should be included as part of an ACO's total costs. Currently, drugs are not included, primarily due to stakeholder concerns that reducing drug utilization could have harmful effects on patient health.

The proliferation of personalized medicines could be especially troublesome for provider-led APMs like ACOs, particularly when new therapies become available. In looking to control total costs, many ACOs lack the expertise to appropriately utilize those expensive therapies in their own populations, and will avoid them to lower their risk to the extent possible.

Although APMs are growing in popularity, their true impact on quality and costs is still evolving. A critical question moving forward will be the impact of APMs on how research and development resources are allocated for therapies that yield potentially life-altering treatments for sometimes significantly smaller subsets of the population.

For drug manufacturers, the amount of research & development, clinical trials, and other resources that go into the drug development process are roughly equivalent for personalized medicines and other therapies. However, once on the market, and because of the smaller populations utilizing them, companies are likely to more heavily weigh how those therapies will be treated by payers. For developers of personalized medicine, this gap represents an opportunity to engage with providers and patients early in the development process.

The ability to work with a wide variety of stakeholders while in the pipeline phase may allow developers to more appropriately set expectations for manufacturers. It may also spur additional research and investments to determine value. Together, stakeholders could develop medical management tools that work towards the measures that matter to ACOs, while appropriately framing the value proposition to help fine tune pricing, clinical trial parameters, and other data collection efforts.

As discussed earlier, although the use of clinical pathways can be arbitrary and sometimes deny patients access to the most effective care for their particular needs, they can be extremely helpful in guiding providers who may not have adequate experience and information available to them, especially when considering a very narrowly tailored personalized medicine. The key will be to provide enough flexibility for providers to take advantage of clinical innovations when appropriate.

Overall, based on interviews with some in the biopharmaceutical industry, the general sense at this time is that APMs have not reached a scale or scope that impacts investment in research and development. But in some instances, especially in the oncology space, there have been initiatives in the private sector that may have a significant effect on the prescribing and utilization of personalized medicines. For example, the WellPoint Cancer Care Quality Program is a pay-for-adherence program that incentivizes physicians to follow pathways chosen by the payer.

As APMs continue to evolve and as policymakers consider how to potentially expand cost-reducing initiatives, it will be important to consider what effect changing incentives and payment systems will have on the decision to invest in personalized medicine. In short, if new incentives begin to hamper access to personalized medicines in a meaningful way, the ability to invest in research and development of highly personalized therapies and diagnostics will likely shift to align with the inflexible payment systems.

CONCLUSION

The case for personalized medicine is clear. Our ability to more accurately predict, prevent, and cure the most vexing of diseases has exponentially increased following the successful mapping of the human genome and our growing understanding of how genetics and biomarkers can reveal a roadmap to more targeted therapies and individualized diagnostics.

As policymakers consider expanding APMs in scope and scale, it will be essential to understand what the downstream effects of changing payment systems can mean for the future of biomedical innovation. The impact on patients of delivery and payment reforms that affect access to targeted treatments for unique characteristics and individualized needs cannot be overstated.

By most measures, the opportunity to coordinate across the care spectrum, meet patients where they are, and address individualized needs has been a long-term shortcoming of the system. Today, APMs continue to proliferate as a means to a more patient-centered health care system and, in most cases, a more data-driven approach than the managed care failures of the 1990s. At the same time, personalized medicine represents a valuable tool in helping to change the health system paradigm in line with the goals of delivery and payment reform.

Policymakers will be called to make some bold choices in the months and years ahead in order to move towards a truly patient-centered health care system and determine whether we will measure success narrowly or comprehensively. Will quality of life, work productivity, and positive contributions to one's family and community be measured as tangible outcomes that we want as a society? Will current congressional budget scoring constraints limit our ability to embrace new innovations and the latest technologies?

Ultimately, it is the belief of PMC and its broad membership that through open dialogue and transparent processes that include all stakeholders, a more efficient and high-quality health system is within reach.

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MISSION

The Personalized Medicine Coalition, representing innovators, scientists, patients, providers and payers, promotes the understanding and adoption of personalized medicine concepts, services and products to benefit patients and the health system. The Coalition's mission is to educate policymakers and the public about the power and potential of individualized health care and raise the profile of personalized medicine so that both patients and the health system will benefit from improved clinical care and increased overall value.



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