

Aligning Incentives: Quality of Care Initiatives and Precision Medicine

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CURRENT SHIFTS IN HEALTHCARE DELIVERY and reimbursement models reflect the changing needs of a health-care field that is rapidly advancing as novel technologies become available. Especially in oncology, the growth of precision medicine is transforming not only the way physicians provide care to their patients, but also the framework for how they are reimbursed. However, the increasing costs of medical treatments and devices combined and the lack of consistent regulation and reimbursement are issues all stakeholders face. These government and managed care initiatives, discussed in this article, are designed to align stakeholder incentives to help improve the quality of care and translate technological advances into improved patient outcomes and decreased healthcare costs.

Government Initiatives (CMS)

The Medicare Access and CHIP Reauthorization Act (MACRA), passed in 2015, established the Quality Payment Program (QPP) as a replacement for the sustainable growth rate formula, with the goal of enabling physicians to provide higher quality care while reducing costs. The QPP consists of 2 methods of aligning incentives: the Merit-based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs).

Under MIPS, Medicare payments are determined by 4 interrelated performance categories: quality, clinical practice improvement activities, use of certified electronic health record technology, and resource use.¹ Of these performance categories, improvement activities consists of activities that fall into 9 subcategories, including population management, care coordination, and achieving health equity, among others (Table 1).¹ Improvement activities that are performed for 90 consecutive days are reported to Medicare for certification and scoring.¹ The goal of the APM program, which is the second track under QPP, is to help physicians overcome reimbursement barriers in the current payment system.² According to a 2015 guide to physician-focused APMs published by the American Medical Association, “APMs are needed that support the delivery of

higher-quality care for patients, at lower costs for purchasers, in ways that are financially feasible for physician practices.”² Physicians who participate in qualified APMs that meet certain thresholds are awarded a 5% annual lump sum payment and are exempted from MIPS.³ Participation in other APMs may help physicians improve MIPS scores.³ Physicians can choose from a variety of APM models to best address the specific barriers and opportunities their practice faces. Each model provides a framework that can be applied to practices of various sizes and specialties to help clinicians improve care, reduce costs, and qualify for incentive payments through MACRA (Table 2).

In the realm of oncology, general improvement opportunities may include more accurate diagnosis and staging, as well as methods to standardize use of treatments. Quality improvement activities may also focus on reducing the incidence of neoplastic symptoms and adverse events, such as nausea, vomiting, and pain, or in reducing complications, especially those that require hospital admissions. Other opportunities for improving quality of care may include optimizing the appropriate selection of patients for imaging studies.³ Successful APMs give providers flexibility in the services they provide, ensure adequate and predictable payments, and hold physicians accountable only for the costs and quality measures that are within their control.²

The Oncology Care Model (OCM) is another government initiative designed to bring about “better care, smarter spending, and healthier people.”⁴ The goal of this payment and delivery model is to align financial incentives to provide higher-quality, highly coordinated oncology care while minimizing costs. The OCM is currently being implemented for beneficiaries of Medicare and 17 participating commercial payers who have the flexibility to design unique payment incentives for their beneficiaries.⁴ A foundational aspect of this model is the use of current medical knowledge and shared decision making between physicians and patients to determine the best course of treatment that addresses each patient’s unique complex care needs.⁴

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TABLE 1. MIPS Improvement Activities Inventory¹

MIPS IMPROVEMENT ACTIVITY CATEGORY	EXAMPLES
Expanded Practice Access	Providing 24/7 access to a clinician, care team, protocol-driven nurse, etc, with access to medical records for advice about urgent care, use of telehealth services or remote specialty care consults, collecting patient experience and satisfaction data to develop quality improvement plans; improving access to services, such as an on-site diabetes specialist or nutritionist
Expanded Practice Access	Participating in an anticoagulation program, rural health clinic, Indian Health Service, or Federally Qualified Health Center; specific glycemic monitoring parameters for diabetic patients; implementing community health status improvement activities; tracking performance to analyze practice patterns and outcomes, especially for vulnerable populations; participating in models such as the Million Hearts Cardiovascular Risk Reduction Model Campaign; participation in clinical data registries run by the government or private entities that use the Qualified Clinical Data Registry (QCDR); empanelment to assign active patients to clinicians; proactive management of chronic or preventive care, including outreach and reminders about services; providing longitudinal and episodic care management; maximizing medication efficiency, efficacy, and safety, and performing medical reconciliation
Care Coordination	Providing specialist reports to the referring physician; timely communication of test results and timely follow-up with patients; participating in the CMS Transforming Clinical Practice Initiative; participating in a CMS Partnership for Patients Hospital Engagement Network; participating in a QCDR; participating in regular care coordination training; documentation of care coordination activities; regularly updating individual care plans for at-risk patients and documenting follow-up in the 30 days after discharge; establishing standards for transitions of care that include efficient lines of communication; participation in a health information exchange and use of structured referral notes
Beneficiary Engagement	Increasing use of patient reported outcomes, such as glucose logs, home blood pressure monitoring, food diaries, etc; participation in a QCDR; participating in Quality Innovation Network Quality Improvement Organization and self-management training programs; accessing enhanced patient portal services; collecting and analyzing patient satisfaction data, promoting collaborative learning network opportunities; encouraging use of patient self-action plans; implementing shared decision making; engaging patients and families to inform improvements in provision of care; using strategies, such as structured goal setting, motivational interviewing, and teach back; using group visits for common chronic conditions; provision of self-management materials at appropriate literacy levels and in patient's native language
Patient Safety and Practice Assessment	Participating in an (AHRQ)-listed patient safety organization and administration of the AHRQ Survey of Patient Safety Culture; registering with the state prescription monitoring program (PMP) and using the PMP before issuing controlled substance prescriptions for 3 or more days; completing the American Medical Association's STEPS Forward program; participating in the Consumer Assessment of Healthcare Providers and Systems Survey or other questionnaires; participation in Joint Commission Ongoing Professional Practice Evaluation initiative or other quality improvement programs, such as Bridges to Excellence; implementing an antibiotic stewardship program; adopting a formal quality improvement model that includes all staff; implementation of fall screening programs to identify at-risk patients and address modifiable risk factors
Achieving Health Equity	Seeing Medicaid patients and patients dually eligible for Medicare and Medicaid and following up in a timely manner; participating in a QCDR; using standard processes for screening patients in regard to social determinants of health, such as food security, housing, and employment; collecting and using patient-reported outcomes data
Integrating Behavioral and Mental Health	Screening schizophrenic and bipolar patients on antipsychotic medications for diabetes; participating in tobacco cessation and alcohol abuse programs, depression screenings and follow-up plans, and suicide prevention programs; integrating facilitation and promotion of mental health and substance use disorder services; offering integrated behavioral health services to patients with behavioral health needs, dementia, or poorly controlled chronic conditions; implementing enhancements to electronic health records to capture additional data on behavioral health
Emergency Preparedness and Response	Participating as a volunteer on a disaster medical assistance teams or a community emergency responder teams; volunteering for domestic or international humanitarian work

TABLE 2. Potential Structures for Physician-Focused APMs²

PAYMENT MODEL	DESCRIPTION
Payment for a high-value service	Physician practices are paid for providing 1 or more desirable services that are not billable under current practices. In return, the physician is accountable for controlling the use of other avoidable services.
Condition-based payment for physician services	Physician practices are allowed to be flexible in the use of diagnostic and treatment options in order to provide the most efficient and effective care without concern that use of a lower-cost service will harm the practice's operating margin.
Multi-physician bundled payment	Two or more practices that are providing complementary services to a patient have the flexibility to redesign their practices to provide high-quality care more efficiently.
Physician-facility procedure bundle	Physicians who deliver procedures at hospitals or other facilities have the flexibility to choose the most appropriate facility and work with them to perform the procedure as efficiently as possible.
Warrantied payment for physician services	Physicians are allowed more flexibility and are held accountable for delivering care with as few complications as possible.
Episode payment for a procedure	Physicians delivering a procedure collaborate with other providers or facilities involved in delivering services related to the procedure to improve outcomes and control spending.
Condition-based payment	Physician practices have the flexibility to use diagnosis or treatment options and collaborate with other providers to address each patient's needs and deliver services most efficiently and effectively.

APM indicates Alternative Payment Model.

Under the OCM, physicians participate in arrangements that are based on episode payment models and include a 2-part payment system that incentivizes coordinated quality care.⁴ The first type of reimbursement is the monthly enhanced oncology services payment, which provide \$160 per beneficiary per month for the duration of the episode of treatment. The second type of reimbursement is a performance-based payment that is given if oncology practices lower their total cost of care while improving quality during the treatment episode.

Other Quality Initiatives

The National Committee for Quality Assurance (NCQA) is a nonprofit organization whose general goal is to improve health care quality. NCQA collaborates with policymakers, large employers, physicians, patients, and health plans to identify key issues, decide how to promote improvement, and determine how to best measure outcomes.⁵ Over the past 5 years, NCQA's yearly statistics have shown continuous improvement in the healthcare delivery system with regard to improved protocols, more efficient practices, and more engaged patients. Overall, these improvements have resulted in reduced morbidity, mortality, and costs.⁵

The standards and performance measures developed by the NCQA are applicable to a wide range of health care

organizations and are used by consumers, media, and health plans to assess quality.⁵ NCQA quality improvement practices generally follow a framework of measuring, analyzing, improving, and then repeating the process. Organizations accredited by the NCQA must meet rigorous standards and report their performance yearly. Accredited health plans must adhere to over 60 standards and report their performance in over 40 areas to maintain accreditation. Currently, accredited plans cover 70.5% of Americans enrolled in health plans.⁵

Unlike NCQA standards, some initiatives in performance improvement are specific to certain disease state areas. For instance, the Institute for Quality (iQ) initiative was developed by the American Society of Clinical Oncology (ASCO) to "promote quality, value, and accountability in cancer care." Several programs have been developed by the Institute for Quality to realize this goal, including the quality oncology practice initiative (QOPI).⁶ The QOPI is a quality assessment program that provides oncologists with standards of practice, a library of quality metrics, and tools to assess care and improve quality. Practices that participate in QOPI can compare themselves to national benchmarks, keep up-to-date with national practice guidelines, and access over 180 quality measures that have been developed by experts in oncology and organized into modules and

pathways to assess the team-based care provided to outpatients. QOPI-certified practices are better prepared to meet the requirements of new payment models and reporting standards established by the government and payers.^{7,8}

The QOPI certification program (QCP) provides a 3-year certification for outpatient oncology practices that apply and continually meet rigorous standards and target measures. Attaining QCP certification demonstrates that a practice is committed to continuous quality improvement and has validated processes for providing high quality care.⁷ The iQ also provides a quality training program that prepares oncology teams to design and implement quality improvement activities while balancing the priorities of running a practice. The program includes 5 focused days of learning via seminars, case examples, small group exercises, and access to faculty and coaches, followed by 6 months of as-needed remote coaching sessions.⁹

CancerLinQ, a subsidiary of ASCO, is an additional resource that collects real-world cancer data and uses big data analytics technology to provide treatment decision support and assist clinicians in providing personalized care.¹⁰ The iQ also provides access to clinical practice guidelines, provisional clinical opinions, and guideline endorsements to aid clinicians in providing high quality care.¹¹

Value of Precision Oncology

A poster based on a retrospective analysis presented at the 2014 ASCO Quality Care Symposium offered proof that genomic targeted therapy was comparable in cost to standard therapies, but reduced the incidence and costs related to morbidities and complications.¹² Genomic targeted therapy is enabled, in part, by companion diagnostics, which are used to inform the risk-benefit ratio of including certain drugs in a patient's treatment plan. These tests can identify the presence or absence of specific mutations or biomarkers to predict a patient's response to a targeted therapy. Having access to this information enables clinicians to select the most effective drug for the patient who is most likely to benefit from it, thereby reducing the toxicities and costs associated with trial-and-error prescribing.¹³

Currently, companion diagnostics account for less than 1% of total healthcare expenditures and make up only a small share of spending on in vitro diagnostics. However, their potential impact on improving patient outcomes and reducing inefficient use of healthcare spending is substan-

tial.¹³ According to the results of a 2016 study, the use of a KRAS companion diagnostic test to select patients with metastatic colorectal cancer for treatment with epidermal growth factor receptor (EGFR) inhibitors, such as cetuximab or panitumumab, resulted in equivalent clinical outcomes and savings that ranged from \$7500 to \$12,400 per patient.¹³ Based on an estimate of 50,000 patients with

metastatic colorectal cancer per year in the United States, the cost savings observed in this study could translate into over \$400 million in savings per year from the regular use of KRAS testing. A poster presented at the ASCO 2009 Gastrointestinal Cancers Symposium estimated these savings to be as much as \$740 million. Variation in these estimates is likely due to the inclusion of costs incurred from laboratory tests, clinical visits, and palliative care and differences in the length of treatment and costs of the drugs at the time each study was conducted. Despite the wide range

in estimates, both studies found that regular *KRAS* testing would result in substantial cost savings.¹⁴

Another test used to direct precision oncology is Oncotype DX, a breast cancer assay that has been used to calculate the recurrence score (RS) in specific subsets of women diagnosed with stage I to III disease, although recent data have been released that show the safety and efficacy of this test in a broader range of patients.¹⁵ Oncotype DX has been found to be reasonable and necessary to contribute to breast cancer diagnosis and major treatment decisions for patients with estrogen receptor-positive disease and 0 to 3 positive nodes.¹⁵ Based on predictions, the Oncotype DX breast cancer assay could increase quality-adjusted survival by 8.6 years and reduce overall costs by \$202,828.¹⁵

The Oncotype DX test predicts recurrence risk in node-negative, estrogen receptor-positive patients with early stage breast cancer more accurately than the current standard of care. In this way, Oncotype DX is especially useful for identifying low-risk patients and determining the need for chemotherapy, as defined by the NCCN guidelines.¹⁵ A study on the utility of the assay found that Oncotype DX was a cost-saving intervention in over two-thirds of probabilistic simulations. Therapy guided by Oncotype DX was associated with a net cost savings of about \$2256 compared with treatment with tamoxifen and chemotherapy, with an incremental cost-effectiveness ratio of \$1944 per life year saved compared with tamoxifen alone.¹⁵ »

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TABLE 3. Cost Variability Between Breast Cancer Regimens¹⁶

	MEDIAN INSURANCE PAYMENTS (LARGEST VARIATION)	MEDIAN OUT OF POCKET COSTS (LARGEST VARIATION)
Patients not receiving trastuzumab	\$82,260 (\$20,354)	\$2727 (\$382)
Patients receiving trastuzumab	\$160,590 (\$46,936)	\$3381 (\$912)

TABLE 4. Physician Behavioral Changes¹⁷

PHYSICIAN BEHAVIORAL CHANGES
Replacing brand name medications with generics when medications are equally effective and have similar toxicity profiles
Replacing expensive brand name medications to less expensive brand name medications when they are equally effective and have similar toxicity profiles
Using molecular diagnostics to more effectively guide therapy
Improving use of evidence-based supportive care strategies
Decreasing use of potentially unnecessary lines of therapy
Limiting late-line therapy to single-agent regimens
Using biologics based on strict label-based indications

A 2007 economic analysis found that therapy guided by the Oncotype DX assay resulted in an increase of 2.2 years in life expectancy compared with tamoxifen alone and similar life expectancy to that seen with tamoxifen and chemotherapy.¹⁵

Clinical Pathways—Improving Quality and Decreasing Costs of Care

According to the results of a 2016 study, the costs of treating breast cancer can vary widely depending on the treatment regimen, regardless of the effectiveness of the regimen.

Because at least 35% of patients with breast cancer will receive chemotherapy, an estimated \$1 billion can be saved yearly by choosing regimens that are equally effective but less expensive.¹⁶

In comparing insurer costs, payments for patients who did not receive trastuzumab as part of their therapy varied by as much as \$20,354, relative to the most common regimen, and out-of-pocket (OOP) costs varied by up to \$382. For patients receiving trastuzumab as part of their treatment regimen, insurer costs varied by up to \$46,936, with OOP costs varying by as much as \$912 (Table 3¹⁶).¹⁶ These large variations in cost arise from differences in the way oncologists practice with regard to drug choice,

supportive care, and referrals to surgery, radiation, or palliative care. Health plans attempt to lower costs by establishing prior authorizations or decreasing fee schedules, but these strategies don't address the differences in practices or the rising costs of cancer drugs.¹⁷ The implementation of clinical pathways, if developed effectively, has the potential to reduce costly variations in physician behavior.

Clinical pathways are evidence-based protocols and best practices developed to improve patient outcomes with the lowest cost regimens.¹⁷ Some barriers to the implementation of clinical pathways include clinician resistance to changing their practice, decreased autonomy in choosing treatment regimens, and time constraints. Physician resistance can be especially strong if treatment pathways are created by insurance companies or external third parties without clinician input.¹⁷

Based on a model implemented in a 2012 study, the first step to creating a pathway program is to take each party's interests into account and align the incentives of all stakeholders, including oncology groups, payers, and pathway management companies.¹⁷ To be effective, the content, structure, and strategy for implementation of pathways should be developed through collaboration

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between physicians and pathway-developing organizations. Before implementing a pathway, it should be shared with all participating physicians so that their experience and expertise can be incorporated.¹⁷ Pathways developed for each specific diagnosis were based on current scientific and clinical evidence with consideration to efficacy, toxicity, and costs. All pathways were designed to include clinical trials, palliative care, and molecular diagnostics.¹⁷

Although the goal of clinical pathways is to reduce costly variation in practice, it is important to allow room for physician judgement and flexibility in treating difficult cases and addressing specific patient needs. As a result, compliance thresholds should be set, with reasonable expectations. An important aspect of the 2012 study was the inclusion of processes that allowed physicians to make appeals or requests for review, especially in advanced cases where standards of care are dynamic. Physicians participating in the study were given a lump sum payment to cover any added expenses and to provide an incentive to adopt and comply with the developed pathways.¹⁷ Practices such as use of appeals and lump-sum payments can play a large role in convincing physicians to participate in clinical pathways.¹⁷

Results of the 2012 study showed substantial oncologist behavior change and reductions in the variation of treatment delivery after implementation of a pathways-of-care program.¹⁷ Physician behavior change through pathways of care were predicted to decrease costs and were proven to lower the rates of emergency department visits and hospital admissions (**Table 4**¹⁷). The total number of distinct treatment regimens used decreased from 168 to 136, with physician compliance increasing from 88% to 95% within the first year. Despite having over 120 unique combinations to choose from, physicians treated a majority of their patients with one of 30 regimens.¹⁷ Overall, the use of clinical pathways benefits the patient, provider, and payer by increasing quality and consistency of care while controlling costs.¹⁷

Current advances in technology and the introduction of new regulations, such as MACRA, in addition to the efforts of established organizations, such as ASCO and NCQA, are influencing the delivery and reimbursement of oncology care. Initiatives such as APMs, the OCM, and QOPI are aimed at improving quality of care while controlling costs. These goals are further made possible by the increasing availability of genomic targeted therapy and companion diagnostic devices, such as Oncotype DX, which allow physicians to better select the right treatments to match the needs of individual patients. ■

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