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US Health Care Reform: The Emergence of Value Based Purchasing and Accountable Care Organizations

A Point of View by Capgemini Consulting

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1. Introduction

On March 23, 2010, the Affordable Care Act was signed by President Obama and health care reform in the U.S. became law. The law is broad, complex, and will be phased in over an extended period of time. Over the last year, the various stakeholders have had a chance to review and analyze how the many components of health care reform may impact their business, customers, and employees. What is clear is that health care reform initiatives have already begun to put pressure on stakeholders to embrace a cost efficient health care system and at the same time reduce the number of uninsured Americans. Payers will have to expand coverage, providers will have to transform their clinical practice to improve patient outcomes, and pharmaceutical companies will face increasing pricing pressures, heightened generic competition, and a new definition of the value of a pharmaceutical product. Two concepts have emerged early that are consistent with reducing overall health care costs and improving health care delivery; Accountable Care Organizations (ACO) and Value Based Purchasing (VBP).

The purpose of this report is to review and provide insight into how the ACO and VBP concepts are expected to support the goals of health care reform, including some challenges associated with their implementation. In addition, this report will attempt to characterize the challenges these models present for pharmaceutical companies.

The concept of the ACO and VBP are related. VBP initiatives will foster a culture of joint accountability among providers to achieve overall clinical and financial outcomes. Because members of ACOs all share a common goal to improve quality and decrease costs among their patient populations, VBP will most likely support the development and expansion of ACOs. Medicare, which will implement VBP, will contribute to bringing the various ACO entities together through sharing quality and cost information for those specific ACO populations.[1] VBP will begin to impact hospitals on October 1, 2012 with payments beginning in 2013.

Under the Medicare Shared Services Program (Section 3022 of the Affordable Care Act), ACOs will be allowed to apply for participating in Medicare with a three year commitment. The Center for Medicare and Medicaid Services (CMS) is considering July 1, 2012 as a start date after receiving feedback from providers on aggressiveness of timelines since the initial published date was January 1, 2012.[2,3] It is assumed that initially between 75 and 150 ACOs would be formed and approved by CMS. The ACOs aim to cover between 1.5 million and 4 million Medicare beneficiaries saving between $170 and $960 million over 3 years. Although the lives covered and money saved are small when compared to the expected Medicare spend of $1.8 trillion during the same period, it is expected that the ACO model will proliferate and extend into privately insured patients, therefore bringing down the overall cost of health care.[4,5]

1 Roadmap for Implementing Value Driven Health care in the Traditional Medicare Fee-for-Service Program, CMS
2 Letter to Donald Berwick, Administrator CMS from Laura Thevenot, CEO ASTRO (American Society for Radiation Oncology), 6th June 2011
3 Summary of 2010 Health care Reform Legislation, American hospital Association, April 19, 2010
4 Leaders Respond to CMS' Proposed ACO Regulations, Health Leaders Media, Apr 2011
5 New ACO Rules Outline Gains And Risks For Doctors, Hospitals, Mar 31, 2011, Kaiser Health News

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2. Value Based Purchasing

Value Based Purchasing (VBP) refers to the methodology that hospitals and other medical facilities employ to manage their costs while providing high-quality care. VBP efforts offer an opportunity to counter the short-term fixation on price with the long-term consideration of total costs and overall value associated with using a technology or product[6]. This report focuses only on hospital VBP. Although recently made law under the Affordable Care Act, VBP has been evolving over years under legislations like the Medicare Modernization Act of 2003, the Deficit Reduction Act of 2005 and the Medicare Improvements for Patients and Providers Act 2008.

2.1. VBP Goals

CMS has been conducting VBP pilots since 2003 for improving care, lowering costs and improving efficiency. The pilots have been of the nature of Pay for Reporting (P4R) (programs where the provider is incentivized to report quality measures, Pay for Performance (P4P) (programs where providers are incentivized to achieve clinical performance targets with a specified patient population) and Pay for Value (P4V) (programs where a particular institutional setting is linked to quality and efficiency parameters). In pursuing VBP in the hospital setting, CMS seeks to align payment policy with the delivery of high quality, efficient care. CMS has defined the following goals for the Medicare Hospital VBP program:[7]

- Improve clinical quality
- Reduce adverse events and improve patient safety
- Encourage more patient-centered care
- Avoid unnecessary costs in the delivery of care
- Stimulate investments in structural components or systems such as IT capability and care management tools and processes that have proved effective in improving quality and efficiency
- Make performance results transparent and comprehensible so that consumers can be empowered to make value-based decisions about their health care and to encourage hospitals and clinicians to improve the quality of care.

6 Comparative Cost Effectiveness and Value-Based Purchasing, Josh Feldstein, Center for Applied Value Analysis
7 U.S. Department of Health and Human Services, Medicare Hospital Value-Based Purchasing Plan Development, 1st Public Listening Session, January 17, 2007

2.2. VBP Implementation

CMS has issued 17 clinical processes of care measures and the Hospital Consumer Assessment of Health care Providers and Systems (HCAHPS) survey (containing 8 measures) for the year 2013, which will be given weights of 70% and 30% respectively, to determine a hospital's Total Performance Score (TPS). TPS will determine incentive payments. The complete list is provided in the Appendix. Individual clinical processes and HCAHPS measures will have equal weights. Incentives will be based both on specified quality thresholds (hospitals will have to perform better than half of all hospitals during the performance period i.e. score above the 50th percentile) and improvement on hospital's own performance (baseline established from July 2009 to March 2010) where the higher of the two scores will be considered. For more details please refer to the Appendix. Incentives will be linearly shared with top hospitals receiving larger incentive amounts, with the incentive decreasing gradually based on the TPS. Payments will be funded by 1% reduction in the hospital's base operating diagnosis related group (DRG) payments in 2013 and will increase by 0.25% until 2017. The VBP program is budget neutral implying that the funds withheld will be paid out to the hospitals with TPS greater than zero. Hospitals will not be considered for incentives if less than four measures apply or if they have less than 100 HCHAPS surveys.[8,9,10,11]

In 2014, CMS proposes to expand the VBP program to add three risk-standardized mortality measures, eight hospitals acquired condition measures, and nine AHRQ Patient Safety Indicator and Inpatient Quality Indicator (IQR) outcome measures (recently added to the Hospital IQR program).

2.3. Challenges in VBP Implementation

Short Timeline

The Affordable Care Act establishes a hospital value-based purchasing program to incentivize enhanced quality outcomes for acute care hospitals by 2012.[12] Payments in 2013 will be based on performance from July 2011 to March 2012. Medicare will link financial incentives or penalties to quality outcomes under this program. The providers have little time to prepare for improving quality of outcomes and its subsequent reporting. Hospitals will have to develop a transition strategy to move from a volume-based to a value-based payment system, a strategy that will take a considerable amount of time to develop and implement.

8 National Association of Public Hospitals and Health Systems, Jan 2011 http://www.naph.org/Links/ADV/VBP-Rule-Summary.aspx
9 Overview of CMS Proposal for Value Based Purchasing, NRC Picker, Jan 2011
10 http://healthreformresourcecenter.ropesgray.com/files/upload/01132011_VBP_AlertPDF.pdf
11 Quality Initiatives: CMS Releases Proposed Rules on Value-Based Purchasing for Hospitals, LarsonAllen, Mar 11
12 Linking Payment to Quality Outcomes, http://dpc.senate.gov/healthreformbill/healthbill65.pdf

Provider Risk

The new quality measures expose hospitals to substantial risks, some of which might be beyond their influence, at least at the program initiation, like the occurrence of a "never event". For example, a wrong blood type might be given to a patient because of incorrect labeling by the blood bank. The hospital intrinsically is not at fault, in this example, but will be penalized nevertheless. Research by the Irving, Texas based VHA Inc. (Voluntary Hospitals of America) shows that 75% of all hospitals covered under VBP stand to lose under the new measures. The research calculated a national median VBP score of 53 when hospitals will need scores higher than 70 to maximize their Medicare reimbursements. Hospitals face an average VBP revenue risk of $888,812 in 2012 and $6.67 million over five years.[13]

Moreover, regional and cultural factors will make it very difficult for some hospitals to score well on patient satisfaction measures outlined by the HCAHPS survey.[14]

2.4. VBP Pilots

2.4.1. Hospital Quality Incentive Demonstration

CMS launched the Hospital Quality Incentive Demonstration (HQID) pilot program on March 31, 2003 in 38 states in United States to test whether paying hospitals for performance (a defined set of quality metrics) would positively impact performance across a whole group of hospitals. During a four year period hospitals improved their quality scores by 17.2% across five clinical areas. It is estimated that if every hospital in US is able to replicate this level of performance, an estimated $4.5 billion and 70,000 lives would be saved each year.[15,16,17]

Since the inception of the HQID program, with its 218 participating hospitals, CMS has awarded about $60 million to top performers. Quality increased substantially for similar hospitals that were not participating in the demonstration but had reported quality information on 'Hospital Compare', making the case stronger for CMS. CMS extended the pilot by three years while changing the payment policy in the extension phase. It rewarded top hospitals as in the past, but now also rewards those who achieved quality above a certain benchmark.[18]

13 Research by Irving, Texas based VHA Inc., http://www.fiercehealthfinance.com/story/medicare-value-based-purchasing-75-percent-hospitals-face-losses/2010-06-30
14 VHA Inc. Sends Comment Letter on VBP to CMS: http://www.marketwire.com/press-release/VHA-Inc-Sends-Comment-Letter-on-Value-Based-Purchasing-Program-Centers-Medicare-Medicaid-1415594.htm
15 https://www.cms.gov/HospitalQualityInits/35_HospitalPremier.asp
16 http://www.ncbi.nlm.nih.gov/pubmed/19810651
17 Medicare News, Department of Health and Human Services, Dec 9 2010
18 Premier Hospital Quality Incentive Demonstration, Fact Sheet, Dec 2010

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3. Accountable Care Organizations

The term Accountable Care Organization (ACO) was coined in 2006 at a Medicare Payment Advisory Commission (MedPAC) public meeting.[19] It's inclusion in the Affordable Care Act has led to its popularity and serious consideration as a leading concept to reduce health care costs while improving the quality of health care delivery. Similar concepts of Health Maintenance Organizations (HMO), Physician-Hospital Organization (PHO) and Independent Practice Associations (IPA) have existed for some time but have lacked the degree of collaboration expected from the ACOs. The intention of an ACO is to bring primary care physicians and specialists, hospitals, health plans and other health care delivery stakeholders into a risk-sharing and savings-sharing model. The organizational model of an ACO will be based on three key features:

i. Local accountability for the effective management of a full continuum of care, with a focus on primary care

ii. Shared savings based on historical trends and adjusted for differing patient populations

iii. Performance measurement including outcomes and patient experience

These three features will be common across ACOs but each organization will behave differently based on its intrinsic size and size of the patient population attributed to it, patient profiles, mix of pro¬viders and perhaps geography.[20] The ACO formation guidelines as suggested by MedPAC are provided in the Appendix.

3.1. ACO Implementation

MedPAC has defined ACOs as a set of providers associated with a defined population of patients, accountable for the quality and cost of care delivered to that population.[21] The providers could include a hospital, a group of primary care providers, specialists, and possibly other health professionals who share responsibility for the quality of care and cost of care provided to patients. Though the current ACO specification is flexible, it is generally accepted that an effective ACO should include at least primary care physicians, specialists and at least one hospital. For the ACO to realize bonuses, it should be able to measure outcomes and costs over a long period of time, distribute the savings achieved amongst participating members and most importantly manage patients across the continuum of care. Some areas in which ACOs will need to build capabilities in order to be successful are highlighted in the Appendix.

19 The History and Definition of the "Accountable Care Organization", Kip Sullivan, Oct 2010, PNHP California
20 Developing Innovative Payment Approaches: Finding the Path to High Performance, Stuart Guterman and Heather Drake, The Commonwealth Fund, June 2010
21 Medical Homes and Accountable Care Organizations: If We Build It, Will they Come? Research Insights, Academy Health, June 2009.

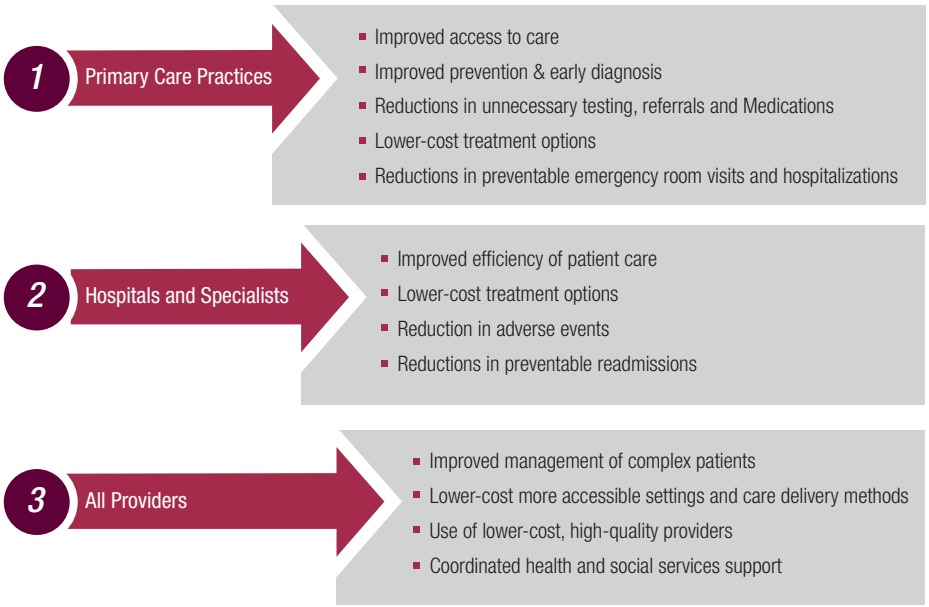
ACO Models

Possible ACO models can be categorized as below in terms of their level of maturity:[22]

- **Level I:** Independent Practice Associations (IPA) or Primary Care Physician (PCP) Groups + Specialty groups + Hospitals
- **Level II:** Multi-Specialty Group + Hospitals
- **Level III:** Physician –Hospital Organization (PHO) or Hospital Medical Staff Organization (MSO)
- **Level IV:** Organized delivery system comprising hospitals, employed and affiliated physicians and other providers like post-acute care

Cost Reduction by ACO Implementation

Following are some suggested mechanisms to reduce health care spending and illusrates how different stakeholders can make contributions to reduce the overall cost of health care delivery within the ACO model.[23]



22 How to Create Accountable Care Organizations, Centre for Health care Quality and Payment Reform, 2009
23 How to Create Accountable Care Organizations, Centre for Health care Quality and Payment Reform, 2009

ACO Operating Model

CMS is considering both a voluntary and a mandatory ACO model. Following are the highlights which briefly describe the two models.[24]

Aspects of a **voluntary** ACO model:

1. Medicare would inform all physicians and hospitals of their current relationships based on Medicare claims data which will allow them to form associations as an ACO.
2. Medicare will assign patients based on the Primary Care Physician (PCP).
3. The incentives of the physician and the hospital will be aligned with the targets of the ACO.

Aspects of a **mandatory** ACO model:

1. Medicare will assign physicians and patients to a hospital. Physicians will be assigned on the basis of their frequency of work with a hospital or that of their patients.
2. Provider payments will be made on a withhold-bonus model based on their performance. Bonuses will be funded by Medicare savings by penalizing providers who fail to meet cost and quality targets.

The targets in both cases will be similar. However, incentives for the voluntary ACO model will not include a penalty clause. MedPAC guidelines on ACO formation is provided in the Appendix.

ACO Quality Metrics

CMS has categorized 65 quality metrics grouped under five domains. Scores from these domains will be the basis for determining shared savings. The domains are as follows:[25]

1. Patient or caregiver experience has seven measures
2. Care coordination has 16 measures
3. Patient safety has two measures
4. Preventive health has nine measures
5. At-risk population or elderly health has 31 measures

24 MedPAC Report of the Congress: Improving Incentives in the Medicare Program, June 2009
25 Leaders Respond to CMS' Proposed ACO Regulations, Health Leaders Media, Apr 2011

3.2. Challenges in ACO Implementation

The challenges in implementation and continuous operations of ACOs are many fold.[26,27,28]

Relationship with Payers

Payers expected to follow Medicare's lead and are concerned that the sanctioning of physician collaboration and physician hospital collaboration may increase provider power, leading to a rise in the cost of services offered. Therefore, although new ACOs might commit to Medicare savings, they may overcharge private insurers and self-funded employers. Providers will need support to develop contractual, legal, financial, and budget targeting relationships with payers that are required to establish the gain-sharing programs and support performance reporting requirements.

New Capability Development for Providers

Although providers will have some of the capabilities needed to run an ACO, they will need to strengthen their managerial, organizational and information technology capabilities, all of which will require a substantial investment of time and resources.

Physician Involvement

The ACO concept will require that the individual physician change the way they perform and evolve their role within the health care system.

- Collaboration between PCPs and Specialists to coordinate patient care will be challenging
- Striking a balance between physician independence and strict guidance for medication and treatment under certain disease conditions will be key to ensure the health of the patient
- Small physician group practices may not have the infrastructure in place to integrate with ACO
- Balancing incentives with penalties may result in strong resistance amongst physicians
- A physician will have to share his savings with all physicians in the ACO. Unless each physician in an ACO is bringing savings, the model will not incentivize individuals to restrain volume

26 Are ACOs risk-ready? Gartner, 15 Feb 2011
27 Implementing Accountable Care Organizations – Berkeley Centre on Health, Economic & Family Security, May 2010
28 MedPAC Report of the Congress: Improving Incentives in the Medicare Program, June 2009

- ACOs will have to aggregate physician practices to offer a breadth of services in order to maintain the health of a population. This will require high initial investment and careful monitoring of contracts to avoid overpayment to physicians
- Physician employment by hospitals is restricted in certain states for out-patient services

Forgone Revenue

A potential decrease in the range of patient services is expected due to the lack of clarity of measuring success in some areas. The savings-sharing model should be such that it should cover for this loss of revenue. Reducing or limiting these services to Medicare beneficiaries, in particular, may have legal ramifications even though the goal is to contain costs and increase efficiencies.

Consistent Spending Targets

Each ACO should have a spending target set in advance. Spending targets for an ACO can be based on an ACO's past experience plus a national allowance for spending growth per capita. Over a period of time, having a single national growth allowance could compress regional variation in spending per capita.

Alternatively the growth allowance can be set as a lower allowance in high-service-use areas (90th percentile of Medicare services) and a higher allowance in low-service-use areas (10th percentile of Medicare services) providing for regional variations of Medicare services. This would place greater pressure, on areas with historically high utilization, to constrain volume.[29,30]

Long Breakeven Period

Initial analysis from Medicare Physician Group Practice (PGP) Demonstration seems to indicate that ACOs will require substantial upfront investments which might take 3-5 years for recovery.[31] This might discourage physician groups from voluntarily joining the program. ACOs will have to design interventions to reduce hospitals readmissions for quick savings and in the long run look to methods like better management of chronic diseases and target interventions directed at specific patient populations.

29 MedPAC June 2009 Report to the Congress (Chapter 2)
30 Regional Variation in Medicare Service Use, MedPAC, January 2011
31 The ACO Model — A Three-Year Financial Loss, March 23 2011, The New England Journal of Medicine, http://healthpolicyandreform.nejm.org/?p=13937

Random Variation of Cost

The cost per patient will vary because of the random variation in the health of the patient. In addition, costs will vary for different diseases and conditions in different ACOs. Measuring performance over a period of three years offers an opportunity to arrive at more stable conclusions. After a three year period, consistent change in spending growth after instituting ACO incentives is more likely to be due to the effect of incentives rather than the random variation in costs. As a remedy MedPAC is considering giving bonuses only to ACOs that meet quality and spending targets every year for three years and assess penalties only on ACOs that fail to meet quality or bonus targets for a three year period.

Measuring performance over a three year period will incentivize providers to maintain long-term relationships with patients, invest in interventions with long-term health benefits, and act as a disincentive for not treating difficult patients.

3.3. ACO Pilots

3.3.1. The Physician Group Practice Demonstration

The PGP demonstration is one example of how a voluntary ACO program could be designed. The program initially ran from 2005 to 2010. It was designed to test the idea that accountability at the practice level would allow Medicare to identify the population of beneficiaries being served, measure cost savings and quality improvement for this group, and share a portion of savings if the practice were able to achieve a certain threshold. Ten physician group practice sites of at least 200 physicians and averaging approximately 500 each and representing a total of more than 200,000 patients participated in the initial program. Round two of the program is scheduled to start in 2011.

The first two years of the PGP program showed that the quality metrics improved for all practices in the program. However, it was difficult to determine whether the program resulted in cost savings. Risk-adjusted patient costs increased for most of the program members. These cost increases could be attributed to better detection and coding of illnesses or an increased number of sick patients coming to the PGP sites.

Key successful factors towards transitioning to an ACO include integration across the continuum of care (with a primary care focus), governance (core values, legal structure), critical mass of patients, patient centricity, data management [clinical decision support, medical management, EHR (Elecronic Health Records), reporting], and tracking costs and utilization.[32,33,34]

3.3.2. Brookings-Dartmouth ACO Pilot

The Dartmouth Institute for Health Policy & Clinical Practice and The Brookings Institution are working with health systems, physicians, commercial health insurers, and state and federal government to engage stakeholders in the challenge of addressing health care delivery system reform by piloting the ACO model. Five diverse provider groups have been chosen to participate:[35]

- Norton Health care in Louisville, KY
- Carilion Clinic in Roanoke, VA
- Tucson Medical Center and affiliated physician groups in Tucson, AZ
- Monarch Health care based in Irvine, CA
- Health care Partners based in Torrance, CA

The General Steps to ACO implementation are:

1. Local providers and payers agree to pilot ACO reform
2. ACO provides list of participating providers to payers
3. Patients are "assigned" to ACOs (based on preponderance of E&M codes)
4. Actuarial projections about future spending are based on historical data
5. Determine/negotiate spending benchmark and shared savings arrangement
6. ACO implements capacity, process, and delivery system improvement strategies
7. Progress reports on cost and quality are developed for ACO beneficiaries
8. At year end, total and per capita spending are measured for all patients
9. Savings under the benchmark are shared between providers and payers

32 MedPAC June 2009 Report to the Congress (Chapter 2)
33 Geisinger's Multi-ACO Efforts May Not Be Easily Replicated, Apr 11, 2011, http://ignitedialogue.com/accountable-care-insights/geisingers-multi-aco-efforts-may-not-be-easily-replicated-1.html
34 PGP to ACO: The "Corps of Discovery", AMGA TEP Group, Shashank Kalokhe – Everett Clinic & F. Douglas Carr – Billings Clinic
35 http://tdi.dartmouth.edu/centers/population-health/policy-core/accountable-care-organizations/

Following is a brief fact summary of the five organizations participating in the ACO pilot:[36,37,38]

Norton Health care, Louisville, KY	▪ A leading hospital & health care system with 44% market share in Louisville ▪ System has 5 hospitals & 12 Immediate Care Centers ▪ 10,900 employees with more than 400 employed medical providers and nearly 2,300 total physicians ▪ 20,000 Medicare patients assigned
Carilion Clinic Roanoke, VA	▪ Integrated Delivery System which is the largest health care provider in SW Virginia ▪ Around 600 physicians and 7 not-for-profit hospitals ▪ 37,000 Medicare patients assigned
Monarch Health care, Irving CA	▪ An Independent Physician Association covering Orange County ▪ More than 800 PCPs ▪ More than 2,500 contracted and independent physicians
Health care Partners, Torrance, CA	▪ An Independent Physician Association covering LA County ▪ More than 1,200 employed and affiliated PCPs ▪ More than 3,000 employed and contracted specialists
Tucson Medical Center Tucson, AZ	▪ More than 80 Providers ▪ Around 7,000 Medicare patients assigned

36 Accountable Care Organization (ACO): Long term commitment to a new vision – Anthem Health, Earnie Schwefler, Nov 2010
37 http://www.nortonhealth care.com
38 http://www.carilionclinic.org/Carilion/About_Carilion_Clinic

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4. Implications for Pharmaceuticals

The ACO & VBP initiatives have the potential for significant impact on the pharmaceutical industry. Their increased emphasis on low cost treatment options and patient outcomes will require the industry to make some fundamental changes in how they do business. In addition, the ACO model and institutions that adopt VBP will further limit physician access by pharmaceutical representatives. The industry will find it necessary to adjust its business model in a manner that allows it to demonstrate and communicate both the clinical and economic impact of its products in these new quality measure driven environments. A shift from sales representative - physician "detailing" to establishing collaborative business to business relationship is already emerging as institutions reexamine how to administer patient care and what partnerships will be synergistic with their efforts. The industry's expertise in marketing, branding, information technology, clinical data management, and clinical study design are all examples of industry areas of core capabilities that may be valuable as new collaborations are explored, evaluated, and implemented.

4.1. Efficacy, Lower Cost of Treatment and Patient Adherence

Instituting more rigorous cost controls while improving productivity and quality will become the norm in health care delivery. The pharmaceutical industry will find it increasingly difficult to justify the price of its products as lower cost; alternative treatments re-emerge as viable options. The value of pharmaceutical products must be closely aligned with the goals and objectives of VBP and the ACO model. Demonstrating this value in unique and innovative ways will provide a strong foundation to achieve the industry's ultimate goal, the utilization of its products in the appropriate manner.

Drug Efficacy

Institutions will measure drug efficacy by more than traditional clinical endpoints. Broader clinical outcomes, along with minimum side-effects and observed adverse events will complete the overall product value picture. Partnering with institutions, especially the ACO models, to capture and analyze real world data is one example of demonstrating drug efficacy in a manner that resonates with institutions. It is important to note that the adoption of EHR by ACOs and other institutions will enable the efficacy of drugs to be compared to one another in a real-time, very detailed manner. Partnering with institutions in the area of EHR is being evaluated by the industry but with limited opportunities being identified.

Adoption of Low Cost Treatment Options

Adoption of generics and low cost treatment options will become the trend as ACOs will embrace cost containment as critical to the success of their organizations. Concepts like "Step Therapy" or the practice of beginning treatment with the safest and least expensive treatment are already emerging as leading practices in the ACO type environment.[39]

Individual prescribers, as members of an ACO, will have a vested interest in prescribing cost effective treatments and following ACO guidelines. As these prescribers are now sharing in the risk assumed by the ACO, their acceptance of safety and efficacy data, when delivered by an individual sales representative, will have diminished value. How a particular treatment performs in the prescribers environment, as demonstrated by EHR aided real world evidence will carry the most weight. The industry will have to show exceptional performance as demonstrated by improved clinical outcomes and cost-effectiveness to maintain the utilization of their branded, higher priced products.[40]

Patient Adherence

Ensuring patient adherence can be a very powerful approach in reducing hospital admissions and unscheduled physician visits, while improving patient quality of life. Improved patient adherence can substantially decrease the overall cost of treatment for any given disease or condition, an outcome that is a top priority for both the industry and organizations that have adopted the ACO model. It is the educational, marketing, and patient behavior expertise and insights that the pharmaceutical industry could leverage to assist ACOs and other institutions in improving patient adherence.

39 How Will Accountable Care Organizations Hit Drug Sales? Ben Come, April 5, 2011, PharmaExec Blog
40 http://www.xcenda.com/ACO-opportunity.asp

4.2. Physician and Institutional Access

The pharmaceutical industry will continue to face unprecedented restricted access to physicians. When company representatives do gain access they will undoubtedly find that physicians have limited flexibility (in the ACO setting, in particular) in their prescribing.

Sales Force Redesign

As physician employment and association with ACOs will reduce their available time for sales reps[41], they will also be highly influenced by ACO product recommendations and burdensome administrative policies that are often associated with VBP. Company representatives must first acquire an in depth understanding of this new environment their physician-customers find themselves in. Interactions between a company representative and a physician will undoubtedly shift to one of quality of care, cost reduction, and how their company's products and services will support those efforts. Sales forces beyond the front line representative have also begun to transform. Identifying opportunities for collaboration, gathering the appropriate information, identifying the key players on the customer side could very well be new responsibilities for an institutional "sales force". The industry will find it necessary to retrain their sales forces so they are in a better position to embrace and execute value-based selling.[42]

Innovative Pricing

Although the industry has years of experience in establishing price-based contracts, it will need to reinvent itself as it learns how stakeholders that are highly influenced by ACOs or VBP define value. Pricing contracts must consider this new definition of stakeholder value and, most likely, demonstrate that the individual pharmaceutical company is willing to take additional risk. Pharma has started to experiment with risk-based models like the Merck-Cigna deal on Januvia, where incentives are created for patients to remain adherent and closely follow their regimen.[43, 44]

Redesigning the traditional institutional sales force and instituting innovative pricing models are two examples of how the pharmaceutical industry can increase its chances of maintaining access to key decision makers within institutions. Other industry transformations will be necessary to keep pace with the emergence of ACOs and VBP, all with the concept of delivering high quality health care while controlling costs.

41 How Accountable Care Organizations (ACOs) will affect Pharmaceutical Sales Representatives, Pharma Reform, 19 Oct 2010
42 http://social.eyeforpharma.com/story/market-access-and-value-based-pricing
43 Merck leads the way to U.S. cost-sharing, Fierce Pharma, Apr 2009
44 Reuters - Cigna, Merck in performance deal on diabetes drugs, Apr 2009

4.3. Opportunity for Collaboration

As the pharmaceutical industry's institutional customer looks to meet the challenges associated with VBP and/or potentially transforming themselves into ACOs, opportunities will also arise that will bring the industry and its customers into unique and innovative collaborations. These collaborations will most likely start in the areas of outcomes research, technology, marketing & branding, and patient education.

The industry's expertise in designing outcomes studies that focus on real world evidence will be seen as very valuable among its institutional customers. Bringing that expertise into institutions to assist them in demonstrating quality improvement, improved patient outcomes, and cost savings will be among the most popular areas of collaboration. In addition to experience with designing both prospective and retrospective trials, knowledge of leading practices in the collection, analysis, and reporting of the data generated is an area where the industry can support and guide the institutional customer.

Working closely with institutions in the area of health information technology is also an area of collaboration that is being explored by the institutions and the pharmaceutical industry. A number of challenges exist however, in forming mutually beneficial collaborations. At the core of the challenge is the fact that the industry tends to focus more on product data as opposed to disease state data. As the industry continues to move more toward providing health solutions versus specific products to treat a specific disease, more potential in this area will be realized.

The area of marketing and branding represents a potential area of collaboration as well. The pharmaceutical industry has developed a significant amount of expertise in this area. The industry has become very effective at branding programs and initiatives, designed to increase the awareness of a product or disease. Institutions realize that they must also establish and maintain a strong brand to form connections with their health professional employees and the patients they treat.

Patient education is the fourth area of collaboration that is likely to emerge as institutions and the industry move to more of a business to business relationship. The pharmaceutical industry has created innovative programs in the "unbranded education" area. Educating patients on topics that will improve overall patient outcomes such as screening for diseases and conditions, behavior modifications to go along with medication (diet, exercise, etc.), and patient adherence to medications have been a focus for the industry for many years. Institutions are now beginning to see the value and impact of these types of programs for their own patient populations.

5. Conclusion

CMS has issued measures under VBP which will capture the performance of hospitals on quality of care and consumer satisfaction. With VBP becoming a reality, it is feasible that soon ACOs may be accepted as one possible solution to controlling spiraling health care costs. Once details of voluntary and mandatory models, patient assignment to ACOs, cost benchmarking, withholds and bonuses are better defined, providers will begin to see the value of a more structured approach to improving the quality of care and controlling costs. There will be many challenges for providers and intuitions as VBP and the ACO model become reality and begin to influence a fundamental shift in how health care is delivered.

Once the pharmaceutical industry identifies the challenges associated with the VBP and the ACO model and the resulting change in behavior of physicians and hospitals under this new framework, they will be able to adapt their business accordingly. The industry will have to shoulder additional responsibility to show the true value of their products, learn to do more with less time with physicians and potentially share the risk of treatment based on outcomes and real world evidence. The industry can become a more valuable partner by sharing their extensive experience in management, clinical development, and technology. The Affordable Care Act is clearly focused on patient health outcomes, including the implementation of VBP and supporting the ACO model. The pharmaceutical industry should take a very close look at the concepts of VBP and ACOs and determine how these initiatives will impact all aspects of their business, from clinical development to a new approach for collaborating with institutional customers; they are the first of many changes to come.

6. Appendices

6.1. Abbreviations

Abbreviation	Full Form
ACA	Affordable Care Act
ACEI	Angiotensin Converting Enzyme Inhibitor
ACO	Accountable Care Organization
AHRQ	Agency for Health care Research and Quality
ARB	Angiotensin Receptor Blockers
CAP	Community-acquired Pneumonia
CER	Comparative Effectiveness Research
CMS	Centers for Medicare & Medicaid Services
DME	Durable Medical Equipment
DRA	Deficit Reduction Act
EHR	Electronic Health Record
ER	Emergency Room
FFS	Fee for Service
HAC	Hospital Acquired Condition
HCAHPS	Hospital Consumer Assessment of Health care Providers and Systems
HMO	Health Maintenance Organization
HMSO	Hospital Medical Staff Organization
IPA	Independent Practice Association
IPPS	Inpatient Prospective Payment Systems
IQR	Inpatient Quality Indicator
LVS (D)	Left Ventricular Systolic (Disorder)
MedPAC	Medicare Payment Advisory Commission
MIPPA	Medicare Improvements for Patients and Providers Act, 2008
MMA	Medicare Modernization Act, 2003
PCI	Percutaneous Coronary Intervention
PCORI	Patient Centered Outcomes Research Institute
PCP	Primary Care Physician
POA	Present on Admission
PHO	Physician-Hospital Organization
PPACA	Patient Protection and Affordable Care Act

Abbreviation	Full Form
P4P	Pay for Performance
P4R	Pay for Reporting
P4V	Pay for Value
SNF	Skilled Nursing Facility
VBP	Value Based Purchasing

6.2. VBP Measures

Following are the measures for the hospital VBP program:[45]

Clinical Process of Care Measure (Weight - 70%)	
Acute Myocardial Infarction	1. Aspirin prescribed at discharge 2. Fibrinolytic therapy received within 30 mins of hospital arrival 3. Primary PCI received within 90 mins of hospital arrival
Heart Failure	4. Discharge instructions 5. Evaluation of LVS function 6. ACEI or ARB for LVSD
Pneumonia	7. Pneumococcal vaccination 8. Blood cultures performed in ER prior to initial antibiotic received in hospital 9. Initial antibiotic selection for CAP in immunocompetent patient 10. Influenza vaccination
Health care Association Infections	11. Prophylactic antibiotic received witihn 1 hr prior to surgical incision 12. Prophylactic antibiotic selection for surgical patients 13. Prophylactic antibiotics discontinued within 24 hrs after surgery end time 14. Cardiac surgery patients with controlled 6AM postoperative serum glucose
Surgeries	15. Surgery patients on a beta blocker prior to arrival that received a beta blocker during perioperative period 16. Surgery patients with recommended venous thromboembolism prophylaxis ordered 17. Surgery patients who received appropriate venous thromboembolism prophylaxis within 24 hrs prior to surgery to 24hrs after surgery
Patient Satisfaction Measures (Weight - 30%)	
Hospital Consumer Assessment of Health care Providers and Systems Survey (HCAHPS) – Patient perspective on hospital care	1. Communication with Nurses 2. Communication with Doctors 3. Responsiveness of Hospital Staff 4. Pain Management 5. Communication about Medicines 6. Cleanliness and Quietness of Hospital Environment 7. Discharge Information 8. Overall Rating of Hospital

45 http://www.gpo.gov/fdsys/pkg/FR-2011-01-13/pdf/2011-454.pdf

Along with these there are a set of Hospital Acquired Conditions (HAC) and "Never Events" or serious medical errors which should never occur for which CMS offers financial disincentives. Under provisions of Section 5001 (c) of the Deficit Reduction Act of 2005, hospitals do not receive payment for cases in which certain conditions occur during hospitalization that were not present on the patient's admission. A number of commercial insurers, including Wellpoint, Aetna, Cigna, and seven Blue Cross Blue Shield associations have ceased never event reimbursement. CMS has included 10 categories of conditions that were selected for the HAC payment provision.[46]

1. Foreign Object Retained After Surgery
2. Air Embolism
3. Blood Incompatibility
4. Stage III and IV Pressure Ulcers
5. Falls and Trauma
   - Fractures
   - Dislocations
   - Intracranial Injuries
   - Crushing Injuries
   - Burns
   - Electric Shock
6. Manifestations of Poor Glycemic Control
   - Diabetic Ketoacidosis
   - Nonketotic Hyperosmolar Coma
   - Hypoglycemic Coma
   - Secondary Diabetes with Ketoacidosis
   - Secondary Diabetes with Hyperosmolarity
7. Catheter-Associated Urinary Tract Infection (UTI)
8. Vascular Catheter-Associated Infection

46 http://www.cms.gov/HospitalAcqCond/06_Hospital-Acquired_Conditions.asp#TopOfPage

9. Surgical Site Infection Following:
   - Coronary Artery Bypass Graft (CABG) - Mediastinitis
   - Bariatric Surgery
   - Laparoscopic Gastric Bypass
   - Gastroenterostomy
   - Laparoscopic Gastric Restrictive Surgery
   - Orthopedic Procedures
   - Spine
   - Neck
   - Shoulder
   - Elbow
10. Deep Vein Thrombosis (DVT)/Pulmonary Embolism (PE)
   - Total Knee Replacement
   - Hip Replacement

The Present on Admission (POA) Indicator requirement and Hospital-Acquired Conditions (HAC) payment provision only apply to Inpatient Prospective Payment Systems (IPPS) Hospitals. The following hospitals are exempt from the POA Indicator and HAC:[47]

1. Critical Access Hospitals (CAHs)
2. Long-term Care Hospitals (LTCHs)
3. Maryland Waiver Hospitals
4. Cancer Hospitals
5. Children's Inpatient Facilities
6. Rural Health Clinics
7. Federally Qualified Health Centers
8. Religious Non-Medical Health Care Institutions
9. Inpatient Psychiatric Hospitals
10. Inpatient Rehabilitation Facilities
11. Veterans Administration/Depart of Defense Hospitals

47 http://www.cms.gov/HospitalAcqCond/03_AffectedHospitals.asp#TopOfPage

Additional measures which will be included in 2014 are: [48]

Condition	Measure
Mortality	30-day heart attack mortality
ACEI	30-day heart failure mortality
ACO	30-day pneumonia mortality
Patient Safety Indicators/ Inpatient Quality Indicators (AHRQ Measures)	Latrogenic pneumothorax, adult
	Post operative respiratory failure
	Community-acquired Pneumonia
	Post operative pulmonary embolism or deep vein thrombosis
	Post operative wound dehiscence
	Accidental puncture or laceration
	Abdominal aortic aneurysm repair mortality rate (with or without volume)
	Hip fracture mortality rate
	Complication/patient safety for selected indicators (composite)
	Mortality for selected conditions (composite)
Hospital-Acquired Conditions	Foreign object retained after surgery
	Air embolism
	Blood compatibility
	Pressure ulcers stages III and IV
	Falls and trauma (Includes: fracture, dislocation, intracranial injury, crushing injury, burn, electric shock)
	Vascular catheter-associated infections
	Catheter-associated urinary tract infections
	Manifestations of poor glycemic control

6.3. VBP Implementation Capabilities

To achieve high quality of health care combined with low cost hospitals will have to achieve high scores on clinical outcomes, patient satisfaction and low volumes of hospital acquired-conditions and preventable readmissions. To do this they will have to shift from a system of treating patients well to a disease prevention system geared towards keeping populations healthy. Some key capabilities in this regard are:[49]

Patient Management: Hospital incentives will depend a lot on patient satisfaction as reported under the Hospital Consumer Assessment of Health care Providers and Systems (HCAHPS) survey. Hence hospitals will need to build closer ties with their patients and ensuring they are satisfied while being treated effectively. They will need to reach out to patients on a regular basis to make sure that they are staying adherent and healthy. Patients will need to be convinced that changes brought about by hospitals to reduce costs wouldn't affect the quality of care and communicating the right message and details will be important to ensure their continued association.

48 SUMMARY OF THE FFY 2013MEDICARE VALUE-BASED PURCHASING PROPOSED RULE, HANYS Feb 2011
49 Will Health care Reform Work? Chad Mulvany, http://staging.hfma.org/Templates/Print.aspx?id=23589

Cost Control: Provider risk will rise substantially in the VBP model. A deep understanding of utilization patterns and health statuses of the patient population will help them to accurately price managed care contracts and develop processes to ensure that patients receive the right intervention in the most cost-effective setting at the appropriate time. Knowing the market and local conditions will be crucial in building cost-effective strategies. Providers might look at other matured industries for best practices to run a tight ship and think of employing principles of lean and six-sigma to cut waste.

Management Structure: The reforms might prompt integration in the health care industry with many Integrated Delivery Systems and hospitals rushing to bring physician networks into their fold. Careful analysis of synergies and adequate management infrastructure will be needed to make sure that new partners are smoothly onboarded with integration of systems, processes and cultures.

IT Infrastructure: Hospital IT systems should be able to capture and report the clinical care and patient satisfaction measures. Sufficient analytical capability should be present to identify bottlenecks and high cost centers. EHR adoption will be a key component in this direction.

6.4. VBP Performance Score Calculation

The VBP score determines the incentive payout for all hospitals as per the calculations shown below.[50,51]

Definitions

- Benchmark Threshold (BT) - Mean of the top decile (90th percentile) of all hospitals' performance scores during the baseline period
- HCAHPS Benchmark Threshold (HCAHPS-BT) - Mean of the 95th percentile of all hospitals' HCAHPS performance scores during the baseline period
- Achievement Threshold (AT) - The median performance score (50th percentile) among all hospitals during the baseline period
- HCAHPS Achievement Threshold (HCAHPS-AT) - The median HCAHPS performance score (50th percentile) among all hospitals during the baseline period
- Performance Score (PS) - The actual performance score of the hospital
- HCAHPS Performance Score (HCAHPS-PS) – The actual score of the hospital on the HCAHPS survey measures
- Clinical Process Score – The actual score of the hospital on the 17 clinical process measures
- Baseline Performance Score (BPS) – The performance score of the baseline period
- HCAHPS Baseline Performance Score (BPS) – The HCAHPS performance score of the baseline period

50 HOSPITAL VALUE-BASED PURCHASING PROGRAM: THE PROPOSED RULE, Regulatory Advisory, American Hospital Association, January 25, 2011
51 Overview of CMS Proposal for Value Based Purchasing, NRC Picker, January 11, 2011

Assumptions

- Each score is rounded off to the nearest whole number
- CMS will set performance standards for each clinical and HCAHPS measure
- Each measure in each domain, clinical and HCAHPS will have equal weight and their sum will determine the score of each category.
- CMS has recommended combining Cleanliness and Quietness in HCAHPS measure as one category and has also proposed not using the 'recommend the hospital' measure.
- For clinical process measures, the score for each domain will be based only on the measures that apply to that hospital i.e. for the measures for which the hospital treats at least the required minimum number of 10 cases.
- Hospital's total points for a domain will be calculated by dividing the sum of Performance Scores of applicable measures by the total points possible and then multiplying by 100 to obtain the hospital's score for that domain.
- Maximum possible score for both clinical and HCAHPS (80 for achievement and 20 for consistency) will be 100 under this formula
- All hospitals with a score above zero will be entitles to incentive payments based on the score in a linear manner. CMS has not specified yet the exact linear scale or what performance score will be necessary to receive maximum payment.
- Hospitals will be not be considered for incentives if less than four measures apply or if they have less than 100 HCHAPS surveys
- CMS proposes to publish on the Hospital Compare website hospital specific information with respect to individual measure scores, condition-specific scores, domain-specific scores and total performance scores

Total Performance Score (TPS) = 70% * (Clinical Process Score) + 30% * (HCAHPS Performance Score)

Clinical Process Score = 100 * ∑{Higher of (Achievement Score or Improvement Score)} / (Total Possible Score on applicable measures)

Achievement Score = 0, if Performance Score < Achievement Threshold, else
10, if Performance Score >= Benchmark Threshold, else
9 * {(Performance Score - AT) / (BT-AT)} + 0.5

Improvement Score = 0, if Performance Score < baseline Performance Score, else
10, if Performance Score >= Benchmark Threshold, else
10 * {(Performance Score – BPS) / (BT-BPS)} – 0.5

HCAHPS Score = ∑{Higher of (HCAHPS Achievement Score or Improvement Score)} + Consistency Score

HCAHPS Achievement Score	= 0, if HCAHPS Performance Score < HCAHPS Achievement Threshold, else 10, if HCAHPS Performance Score >= HCAHPS Benchmark Threshold, else {(HCAHPS Performance Score – 50) / 5} + 0.5
HCAHPS Improvement Score	= 0, if HCAHPS Performance Score < HCAHPS Baseline Performance Score, else 9, if HCAHPS Performance Score >= HCAHPS Benchmark Threshold, else 10*{(HCAHPS Performance Score – HCAHPS-BPS)/(HCAHPS-BT-BPS)}-0.5
Consistency Score	= 0, if any HCAHPS Performance Score measure <= any HCAHPS baseline Performance Score measure of any hospital 20, if all HCAHPS Performance Score measure >= HCAHPS Achievement Threshold 2 * (Lowest Percentile of any HCAHPS measure) / 5 – 0.5

6.5. ACO Implementation Capabilities

It will take some time for provider organizations, even the most prepared ones, to be fully accountable for the costs and outcomes of all their patients. Some broad areas that the ACOs will need to build capabilities are as follows[52]

Core Competency	Focus Area
Leadership	▪ Strategy on centralized or decentralized organization ▪ Fostering Innovation
Legal and Governance	▪ Regulatory Compliance ▪ Contract Management ▪ Relationship Management with other stakeholders
Operational	▪ Patient monitoring throughout continuum of care ▪ Tracking and reporting cost and quality parameters ▪ Supply Chain Efficiencies
Information Technology	▪ Exchange of data between different stakeholders ▪ Adoption of EHR

6.6. ACO Formation Guidelines

MedPAC has suggested some guidelines that an ACO should have:[53]

1. ACOs should be fairly large (at least 5,000 patients) to make it possible to distinguish actual improvement from random variation on a reasonably consistent basis.
2. A spending target set in advance - based on its past experience plus a national allowance for spending growth per capita or set a lower allowance in high-service-use areas and a higher allowance in low-service-use areas.

52 Top Actions for Health care Delivery Organization CIOs: Choose a Clear ACO Approach, Gartner, April 201153
53 MedPAC June 2009 Report to the Congress (Chapter 2)

3. A formal organization and structure that allows them to make joint decisions on capacity.
4. Have private insurers join Medicare to overcome incentives in Fee for Service (FFS) payment systems in order to expand capacity and volume.
5. For bonus sharing a voluntary and a mandatory model has been suggested. The former suggests constraining FFS rates since Medicare won't be able to keep all savings anymore and unless Medicare's share of true savings from ACOs' efforts to reduce spending exceeds the cost of bonuses paid, Medicare spending will not be reduced. The latter bonuses will be funded by the combination of true shared savings and a penalty assessed on poor performers. Under the mandatory model, ACOs with high cost and low quality scores would receive lower Medicare payment rates.

MedPAC has suggested two models for ACO formation. Following is a detailed comparison of the voluntary and the mandatory models as submitted by MedPAC in its report to Congress.[54]

	Voluntary ACO Model	Mandatory ACO Model
Organization	▪ Physicians and hospitals choose to form ACO and be held jointly responsible for the quality of care and the level of spending on their Medicare patients	▪ All physicians and hospitals are assigned to virtual ACOs and held jointly responsible for the quality of care and the level of spending on their Medicare patients
Incentives	▪ Physicians and hospitals agree on how to share revenues, or the government mandates a bonus structure ▪ No Penalties for poor performers ▪ Difficult patients could be dropped or transferred to non-ACO providers ▪ Providers face no risk	▪ Medicare administers a system of withholds and bonuses ▪ Penalties for members with low quality and high costs ▪ ACOs could drop patients, but another ACO would continue to be responsible for cost and quality ▪ Providers face some risk
Implications	▪ ACO bonuses would be funded with shared savings and by restraining FFS rates. This would result in relatively lower FFS rates than under a mandatory system given any set level of Medicare spending. ▪ Patients free to choose physicians	▪ ACO bonuses would be funded by shared savings and penalties/withholds for providers with poor quality and high costs ▪ Patients free to choose physicians

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