Achieving Patient-Centered Medical Home (PCMH) and Meaningful Use Status – How to transform the Physician Practice in light of Health Reform

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I. Introduction

Health care reform: What are the current trends?

The healthcare industry is transforming before our eyes. accountable Care Organizations (ACOs) are flourishing. With the most recent approvals, the latest Medicare figures put the number of ACOs in the Medicare Shared Savings Program (“MSSP”) at approximately 360. In 2014 alone, Medicare approved 123 new organizations. This does not even count the number of other types of ACOs or ACO-type entities in the United States. Payers like UnitedHealthcare are partnering with large organizations, like Coastal Medical in Rhode Island to form commercial ACOs1. Pharmacies like Walgreens are doing the same, forming ACOs with large medical groups in New Jersey, Florida and Texas2. Large Medical groups are forming organizations and Hospitals are buying up practices again. Small physician groups are giving up their autonomy for a better less costly alternative by joining larger groups and hospital systems.

Why all this attention? With the United States (“US”) spending approximately $2.8 trillion on healthcare annually (nearly 18% of our Gross National Product), while ranking among the worst in terms of quality and outcomes, health care reform is demanding consolidation, looking at healthcare delivery reforms, payment reforms, and improved patient engagement and quality outcomes. However, the only way to achieve this is to transform the way we practice medicine and to be able to track data and information via systems.

Why are Primary Care Physicians (“PCPs”) critical to healthcare reform?

Primary care is a foundation of the US health care system. Primary care clinicians are often the first point of contact for an individual; thus, patient access to care is an important issue. Clinicians must have a broad knowledge of many health care conditions and often follow their patients over years; thus, the quality of the clinician/patient relationship and the clinician’s ability to track care over time plays a key role in outcomes. Many PCPs and allied health professionals such as advance practice nurses need to refer patients to specialists; thus, magnifying how important communication is among providers - and often challenging.

How is coordination of care communicated?

Just as patient-centeredness is an integral part of the new way of primary care fostered by healthcare reform, so too is a practice’s ability to track a patient’s care over time and across settings. The federal government is making a major investment in encouraging clinicians to use

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2 http://news.walgreens.com/press+releases/general+news/aco.htm
health information technology to improve the quality of care. The amount of clinical information for some patients – particularly those with chronic illnesses – and the fragmented nature of the U.S. health system make this aspect of primary care challenging. Experts agree that health IT can help clinicians coordinate patient care, but merely having an electronic health record system in a practice is not enough. Health Information Technology or Health IT can capture accurate information, while providing information to the clinician on outcome measures on a timely basis through reports summarizing the clinical data pulled from the patient’s electronic health record systems (EHR). In turn, these same reports can be used to review trends among population groups, which may include visit frequencies, medication dosage and treatment course changes, and to track patient progress and patient education. Health IT can expand performance improvement in all clinical activities by allowing practices to compare patient results and provider performance among providers and practices. The Health IT itself must be useful, and practices must use it to achieve the goals of coordination and high quality of care.

II. Patient Centered Medical Homes and Meaningful Use

What is Meaningful Use and how does it tie into Healthcare Reform?

How do we get data? By using EHR and registry programs to capture data we collect from our patient population and perform analytics.

Healthcare reform has introduced us to a way in which to incentivize physicians and hospitals to use electronic health record systems and registry programs to be able to eventually capture the data and analyze the data by using the systems in a Meaningful Way. They call this achieving “Meaningful Use”. Meaningful Use is a stimulus program which says to an eligible provider or a hospital, that starting in October 1, 2010, if you purchase and start using an EHR “in a meaningful way” the government will pay you money for each year you “attest” to using your EHR system in a meaningful way. There are three (3) stages of Meaningful Use.

- **Stage 1** - CMS challenges providers and hospitals to start using their systems in a meaningful way and to start collecting data.
- **Stage 2** - CMS challenges providers and hospitals to advance their thinking with regard to data collection and looking at clinical processes and measuring outcomes. Among other criteria, Stage 2 supports ways to improve patient care through enhanced clinical decision support, care coordination, and patient engagement.
- **Stage 3** CMS continues to challenge providers and hospitals to improve their clinical processes to advance the study of outcomes.

How does the PCMH model tie into healthcare reform?

After more than 30 years of academic study, research findings demonstrate that countries and health systems that heavily invest in primary care have better health outcomes at lower total cost. The first concept of transforming our practices stemming from healthcare reform is the Patient-Centered Medical Home (“PCMH”), or Medical Home model. PCMHs not only focus on compassionately treating illness and injury when they occur, but also on prevention and wellness. As ACOs have begun to spring up on the national landscape, their core statutory requirement is patient-centered care. So, not surprisingly, primary care and patient-centered medical homes are beginning to dominate discussions as one of the most promising models to deliver cost-effective and high quality care, particularly for patients with chronic health conditions. The PCMH continues to play an essential role in strengthening the larger healthcare
system, specifically ACOs and the emerging medical neighborhood model. Many of the nation’s highest performing ACOs embrace a strong PCMH component, and for this reason, PCMHs are considered well-positioned to lead and drive change across ACOs.

What is a Medical Home?

Well, it’s not a place or a nursing home, but rather a medical philosophy. The PCMH is an approach to providing comprehensive primary care for children, youth and adults. The PCMH is a health care setting that facilitates partnerships between individual patients, and their personal physicians, and when appropriate, the patient's family.

While there is no single definition of a PCMH, most PCMH models share common principles of quality and safety components, including: (1) optimal, patient-centered outcomes, (2) evidence-based medicine and clinical decision support tools to guide decision making, (3) accountability of providers for continuous quality improvement through voluntary engagement in performance measurement and improvement, (4) patient participation in decision making and sought feedback to ensure patients’ expectations are met, (5) information technology utilized appropriately to support optimal patient care, performance measurement, patient education and enhanced communication, (6) a voluntary recognition process conducted by an appropriate nongovernmental entity to demonstrate that the practice has capabilities to provide patient-centered services consistent with the medical home model, (7) patient and family participation in quality improvement activities at the practice level, and (8) enhanced access to health care available through systems such as open scheduling, expanded hours and new options for communication between the patient, the provider and staff.

Joint Principles Leaders from the American Academy of Family Physicians (“AAFP”), the American College of Physicians (“ACP”) and the American Osteopathic Association (“AOA”) together published the Joint Principles of the Patient Centered Medical Home (the “Joint Principles”).\(^3\) The Joint Principles establishes the following characteristics as necessary for any PCMH:

- **Personal physician** - each patient has an ongoing relationship with a personal physician (“Personal Physician”) trained to provide first contact, continuous and comprehensive care.

- **Physician directed medical practice** – the Personal Physician leads a team of individuals at the practice level who collectively take responsibility for the ongoing care of patients.

- **Whole person orientation** – the Personal Physician is responsible for providing for all the patient’s health care needs or taking responsibility for appropriately arranging care with other qualified professionals. This includes care for all stages of life: acute care; chronic care; preventive services; and end of life care.

- **Care is coordinated and/or integrated** across all elements of the complex health care system (e.g., subspecialty care, hospitals, home health agencies, nursing homes) and the patient’s community (e.g., family, public and private community-based services). Care is facilitated by registries, information technology, health information exchange and other

means to assure that patients get the indicated care when and where they need and want it in a culturally and linguistically appropriate manner.

- **Quality and Safety** – Quality and safety are hallmarks of the medical home model
  - Practice advocate for their patients to support the attainment of optimal, patient-centered outcomes that are defined by a care planning process driven by a compassionate, robust partnership between physicians, patients, and the patient’s family.
  - Evidence-based medicine and clinical decision-support tools guide decision making.
  - Physicians in the practice accept accountability for continuous quality improvements through voluntary engagement in performance measurement and improvement.
  - Patients actively participate in decision-making and feedback is sought to ensure patients’ expectations are being met.
  - Health IT is utilized appropriately to support optimal patient care, performance measurement, patient education, and enhanced communication.
  - Practices go through a voluntary recognition process by an appropriate non-governmental entity to demonstrate that they have the capabilities to provide patient centered services consistent with the medical home model.
  - Patients and families participate in quality improvement activities at the practice level.

- **Enhanced Access** – through systems such as open scheduling, expanded hours, and new options for communication between patients, their personal physician, and practice staff.

- **Payment Reform** -- appropriately recognizes the added value provided to patients who have a patient-centered medical home. The payment structure should be based on the following framework.
  - It should reflect the value of physician and non-physician staff patient-centered care management work that falls outside of the face-to-face visit.
  - It should pay for services associated with coordination of care both within a given practice and between consultants, ancillary providers, and community resources.
  - It should support adoption and use of Health IT for quality improvement.
  - It should support provision of enhanced communication access such as secure e-mail and telephone consultation.
• It should recognize the value of physician work associated with remote monitoring of clinical data using technology.

• It should allow for separate fee-for-service payments for face-to-face visits. (Payments for care management services that fall outside of the face-to-face visit, as described above, should not result in a reduction in the payments for face-to-face visits).

• It should recognize case mix (i.e. severity of illness) differences in the patient population being treated within the practice.

• It should allow physicians to share in savings from reduced hospitalizations associated with physician-guided care management in the office setting.

• It should allow for additional payments for achieving measurable and continuous quality improvements.

**Illustrative Legislative Example**

An illustrative description of a PCMH that captures these common principals can be found under California law, 2011 SB 393, set forth below:

• Defines “medical home,” “patient-centered medical home,” “advanced practice primary care,” “health home,” “person-centered health care home,” and “primary care home” to all mean a health care delivery model in which a patient establishes an ongoing relationship with a physician or other licensed health care provider acting within the scope of his or her practice, working in a physician-directed practice team to provide comprehensive, accessible, and continuous evidence-based primary and preventative care, and to coordinate the patient’s health care needs across the system in order to improve quality and health outcomes in a cost-effective manner.

• Requires medical homes to provide:
  
  • Individual patients with an ongoing relationship with a physician or other licensed health care provider acting within his or her scope of practice, who is trained to provide first contact and continuous and comprehensive care, or if appropriate, provide referrals to health care professionals that provide continuous and comprehensive care;

  • A team of individuals at the practice level collectively taking responsibility for the ongoing health care of patients, who takes responsibility for providing all of a patient’s health care needs or for appropriately arranging health care by other qualified professionals including making appropriate referrals;

  • Coordinated care that is integrated across all elements of the complex health care system – including mental health and substance use disorder care, and the patients’ community – and that is facilitated, if possible, by registries, information
technology, health information exchanges, and the care in a culturally and linguistically appropriate manner; and

- Quality and safety components, including: (1) optimal, patient-centered outcomes, (2) evidence-based medicine and clinical decision support tools to guide decision making, (3) accountability of providers for continuous quality improvement through voluntary engagement in performance measurement and improvement, (4) patient participation in decision making and sought feedback to ensure patients’ expectations are met, (5) information technology utilized appropriately to support optimal patient care, performance measurement, patient education and enhanced communication, (6) a voluntary recognition process conducted by an appropriate nongovernmental entity to demonstrate that the practice has capabilities to provide patient-centered services consistent with the medical home model, (7) patient and family participation in quality improvement activities at the practice level, and (8) enhanced access to health care available through systems such as open scheduling, expanded hours and new options for communication between the patient, the provider and staff.

Is the concept of PCMH new?

The American Academy of Pediatrics (“AAP”) introduced the medical home concept in 1967, initially referring to a central location for achieving a child’s medical record. In its 2002 policy statement, the AAP expanded the medical home concept to include these operational characteristics: accessible, continuous, comprehensive, family-centered, coordinated, compassionate, and culturally effective care. The concept of the medical home was started by the National Committee for Quality Assurance (“NCQA”), as an organization that manages voluntary accreditation programs for individual physicians, health plans, and medical groups. NCQA’s Patient-Centered Medical Home (PCMH) Recognition Program evolved into a program initially initiated in 2003 with support from The Robert Wood Johnson Foundation, The Commonwealth Fund and Bridges to Excellence and in 2008 turned into the Physician Practice Connections®– Patient-Centered Medical Home™ (PPC®-PCMH™) Recognition program. The PPC-PCMH 2008 program was developed with input from the American College of Physicians (“ACP”), the American Academy of Family Physicians (“AAFP”), the American Academy of Pediatrics (“AAP”) and the American Osteopathic Association (AOA) and their published 2007 Joint Principles of the Patient-Centered Medical Home.

NCQA Recognition

For many, NCQA PCMH is “The Gold Standard” for Primary Care Transformation. NCQA’s PCMH Recognition program is the most widely used method for transforming primary care practices into medical homes. Payers like UnitedHealthcare and Blue Cross Blue Shield of Michigan have adopted the PCMH model for their practices because it has shown to increase patient outcomes, patient engagement and reduce costs.

The following statistics demonstrates how the NCQA PCMH model has grown:

- The program has grown from 214 clinicians at 28 practices in 2008, to over 6,000 practices and almost 30,000 recognized clinicians in 49 states as of September 2013.

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• Each month, more than 150 practices apply for recognition;
• There are close to 400,000 primary care providers eligible to participate in the program;
• The Department of Defense is working with NCQA to help its primary care practices become PCMHs;
• The Department of Health & Human Services is working with NCQA to help community health centers transform into medical homes;
• Government and private sector initiatives in 38 states have used the NCQA model to support the spread of medical homes.

So, what does Meaningful Use have to do with PCMH?
The principles are very much in alignment with each other. Most of the twenty (20) Stage 1 Meaningful Use core and menu set measures, see appendix A, are imbedded in the 6 standards, 27 elements and the 147 factors of the 2011 PCMH standards. In fact, the 2014 PCMH Standards and Guidelines were developed to align with the Stage 2 set of Meaningful Use guidelines.

The path to recognition as a PCMH

So, how do you become recognized as a PCMH? Not all physicians can embrace the concept of using evidence-based medicine, a team approach to care and the use of standing orders, coordination of care, proactive outreach, or using their electronic system to fifty (50%) percent of its capabilities. The biggest challenge a physician practice faces is embracing change. Some practices are going through the motion of becoming a PCMH because their participation in the hospital, group practice or ACO has mandated it as part of their employment or participation agreement. Other practices are doing it because they are already practicing medicine proactively, as a team and would like to earn the distinction of becoming a NCQA recognized “Medical Home”. Some of the biggest hurdles we see in a practice going through their transformation process are the inability to think outside the box or understand the broader concepts that the PCMH designation fosters or, better said, ties together.

To successfully implement a PCMH, physicians and other caregivers need to change their attitude toward healthcare reform from reactive to proactive and embrace some of the following examples:

• Team based approach to care – using the clinical team (medical assistants and nurses) to the full extent of their licensure, using standing orders and visit protocols to administer immunizations and collect health information;
• Population health - using patient data and outreach methods to proactively remind patients about the importance of having screening mammograms, colonoscopy, flu shots, chronic care follow ups; and
• Patient engagement- introducing motivational interviewing techniques to enable patients to really understand their chronic conditions and what the clinical team is trying to convey to them about the importance of staying on their medication, quitting smoking, having screenings, coming in for their regular follow visits with regard to their chronic conditions.
The path to implementation

As mentioned earlier, there are 147 factors, which are a series of yes and no questions. For each “Yes” answer, the practice/provider has to provide some sort of proof or documentation that supports the “Yes” answer that the practice does in fact do what the question asks. For instance, in standard 1A1: Providing Same Day Appointments, the practice will have to:

1. Write a policy to describe how and why the practice has same day appointments;
2. Demonstrate how the practice monitors and tracks their same day appointments, via log or report;
3. Provide an example of what the appointment schedule looks like via a screen print, or print screen.

The Scoring:

There are three levels of Recognition provided by NCQA for the program. A practice needs only get 35 points for a level 1, 60 points for a level 2 and 85 points for a level 3.

The difference of the practices’ or providers’ recognition levels is often based on their motivations to pursue this program. The characteristics a practice or provider exhibits for each level of recognition they receive may be categorized in the following way:

Level 3 – The practice or provider has dramatically embraced the PCMH culture. (some would say they drank the "Kool-Aid")

Level 2 – The question of the day “What happened to the level 2’s?”

Level 1 – The practice or provider demonstrates a deferential attitude, non-believer, they may be a paper-based practice, and/or a practice going through the motions to secure recognition for recognition sake.

Best practices:

Many providers experience their "aha!" moments when they are trying to connect the dots from a policy stage to the workflow and implementation stage.

Here are some examples:

- Team approach to care: One of the biggest hurdles to embracing the PCMH model is embracing the concept that the medical assistants can be and should be used to the fullest extent of their license. Many providers do not trust them to even take a blood pressure, however their training often includes blood pressure readings, immunizations and performing electrocardiograms or EKG’s (measures of the electronic activity of the heart). Without utilizing the value that these members provide, physicians will continue to waste time on tasks that should be left for support staff to do so they can spend more face to face time with the patient.

- Proactive outreach: There was a time when providers used paper charts they had a manual recall or reminder system in place so that patients could be reminded that they were due for their physical, mammogram or flu shot. Now with EHRs, most physicians forget that they once provided these services to their patients because they don’t know
how to use their system to track these visits. Being able to generate patient lists where we can tell who has not had certain preventive screenings and immunizations and which chronically ill patients have missed their 3 or 6 month follow up appointment is critical. Most of the EHR systems have built in reminders that either need to be turned on or customized to provide the type of reminders that the practice can utilize. Some of them even offer the option to send text or emails to patient portals instead of sending letters or telephone calls.

- **Barriers to medical care**: Are patients being asked if they have experienced any barriers to their medical care for example, problems with transportation or access to their medications? There is a provider in NJ who thought that he had a very affluent patient population that didn’t experience any financial barriers or transportation issues until urged to actually ask patients about any significant barriers to their medical care. The answers were astounding. Patients were having problems getting to their medical appointments because they depended on family members, and were experiencing the same financial issues in purchasing their medications as they have also fallen prey to the “donut hole” scenario.

- **Patient engagement**: The idea of patient communication is not a new concept. Providers say that they always tell their patients that they have to take their medicine and that they have to stop smoking. Some physicians talk about “babysitting” their patients and that somehow the provider is ultimately responsible for a patient’s health and wellbeing. At what time is the patient responsible for their own outcomes? This is where the new communication styles come into play. If the entire care team is trained to use the ‘Teach Back” method where clinicians are not talking at the patient they are talking with the patient and asking the patient about the top three things they understand about what they were just told.

**The Proof:**

The Patient-Centered Primary Care Collaborative recently released a report (*The Patient-Centered Medical Home’s Impact of Cost & Quality: An Annual Update of the Evidence 2012-2013*, published January 2014) that summarized findings from PCMH demonstrations and concluded that findings from PCMH demonstrations show success in increasing the quality of care and in reducing cost of care on some measure. In the academic literature, a recent article also found reduced use of hospitalization and emergency room visits and overall savings (Fields, Leshen, Patel, 2010). Another study evaluating a PCMH demonstration project in an integrated group practice showed significant improvement in patient and provider experiences and in the quality of clinical care (Reid, 2009). More specifically, the Patient-Centered Primary Care Collaborative just released the following statistics about the benefits of the PCMH model:

A summary of key points from this year’s report include:

1. **PCMH studies continue to demonstrate impressive improvements across a broad range of categories including**: cost, utilization, population health, prevention, access to care, and patient satisfaction, while a gap still exists in reporting impact on clinician satisfaction.

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5 Available at [http://www.pcpcc.net/content/pcmh-outcome-evidence-quality](http://www.pcpcc.net/content/pcmh-outcome-evidence-quality)
While recognizing that "one size does not fit all," these twenty (20) studies found that PCMH initiatives continue to demonstrate improvements across a number of metrics in peer-reviewed (academic) and industry-generated studies. The most common reported metrics include:

- **Decreases in the cost of care**, such as per member per month (PMPM) costs, return on investment, and total cost of care (61% of peer-reviewed and 57% of industry-generated studies);

- **Reductions in the use of unnecessary or avoidable services**, such as emergency department or urgent care visits (61% of peer-reviewed and 57% of industry-generated studies), inpatient admissions (31% peer reviewed and 57% industry-generated studies), and hospital readmissions (13% of peer-reviewed and 29% of industry-generated studies);

- **Improvements in population health indicators and increase in preventive services**, such as better controlled HbAlc. blood pressure, and LDL levels (31% of peer-reviewed and 29% of industry-generated studies) and increases in screening and / or immunization rates (31% of peer-reviewed and 29% of industry-generated studies) (see anecdote below from Atlantic City, New Jersey area);

- **Improvements in access to care**, such as improved overall access to primary care clinicians, as well as non-face-to-face visits (31% of peer-reviewed and 29% of industry-generated studies);

- **Improvements in patient satisfaction**, such as overall satisfaction, recommending the practice to family and friends, and satisfaction with provider communications (23% of peer-reviewed and 14% of industry-generated studies); and

- **Future studies should include clinician satisfaction** as part of PCMH evaluation studies that measure cost and utilization given the importance of strengthening and enhancing the primary care workforce. Only a single study found here, the University of Utah's "Care By Design" program, overtly measured improvements in clinician satisfaction.

Further supporting the PCMH, recent research finds that the longer a PCMH model of care has been in place, the greater the cost savings and improvement in quality and outcomes.

2. **The PCMH continues to play a role in strengthening the larger health care system, specifically Accountable Care Organizations and the emerging medical neighborhood model.**

As private and public sector support for the PCMH continues to build, the health care sector continues to recognize the foundational role of the PCMH in delivery models such as ACOs and the emerging medical neighborhood model. Many of the nation's highest-performing ACOs embrace their strong PCMH component, and for this reason, PCMHs are well-positioned to lead and drive change across ACOs. Initial ACQ evaluation results from CMS suggest that many early adopters have indeed improved the cost effectiveness of care delivery and received shared
savings as a result. Many of the improvements can be attributed to PCMH-like features, including innovative approaches to care coordination, team-based care, and chronic disease management. As evaluations of ACOs, integrated health systems, and the medical neighborhood continue, the PCMH will be essential to driving improvements in cost, quality, and outcomes.

3. **Significant payment reforms are incorporating the PCMH and its key attributes.**

Paying for a health care system that invests in primary care and the PCMH is imperative. One of the most promising payment reforms, reforms of 2013 includes recent Congressional activity to repeal the Medicare Sustainable Growth Rate or “SGR”. If passed into law, these reforms will result in a major step toward moving the US health care system away from a fee-for-service or “FFS” model, to one that rewards quality, efficiency, and innovation. The proposal specifically names the PCMH as a supportive framework for alternative value-based payment models that reward quality and value. Significant strides were also made this year in the private sector, as commercial health plans increasingly transitioned their PCMH ‘demonstrations' or pilots into a standard business operation (i.e. incentivizing primary care and PCMHs with PMPM payments or care coordination fees).

The findings are indeed encouraging and the evidence base for the model continues to build at a rapid pace. While we need to be cautious about over-promising what the PCMH alone can deliver our review of the recent literature affirmatively shows improvements across a number of categories. Our review also suggests some gaps in the evidence and ways to improve future PCMH studies. More robust analyses regarding how PCMHs function, transform and improve outcomes for all patients and their families are critical to the long-term success of primary care, as well as helping the US to achieve much needed, broad-based delivery reform.

**Illustrative Case Studies:** The January 2014 PCPCC Annual Update of the Evidence Report provided the following case study snapshots:
BlueCross BlueShield of Michigan Physician Group Incentive Program

**Michigan (statewide), 3 million patients**

**Publication Date: July 2013**

Blue Cross Blue Shield of Michigan’s PCMH program, one of the largest in the nation with nearly 2,500 practices, yielded significant improvements in quality and preventive care. In fact, the health plan estimates savings of $155 million in the program’s first three years. These avoided costs represent the savings achieved relatively early in the program’s history and factor in costs at all practices in the program, not just those that had been designated as PCMH-based practices. The program demonstrated that cost savings achieved by highly developed PCMH practices are substantially greater. The analysis also shows that, when physicians fully transform their practices to the PCMH model, it results in higher quality and improved preventive care.

### RESULTS
- 13.5% fewer pediatric ED visits
- 10% fewer adult ED visits
- 17% fewer inpatient admissions
- 6% fewer hospital readmissions
- Savings of $26.37 PMPM
- $155 million in cost savings

UPMC Health Plan

**Pennsylvania, 23,390 patients**

**Publication Date: July 2013**

UPMC Health Plan is part of a large, integrated delivery and financing system headquartered in Pittsburgh, Pennsylvania. From 2008 through 2010, sites participating in the plan’s PCMH pilot achieved lower medical and pharmacy costs; and lower utilization of services such as ED visits, hospital admissions and readmissions. The plan also experienced a 160 percent return on the plan’s investment when compared with nonparticipating sites. As part of the initiative, UPMC provided each participating site with a practice-based nurse care manager, who was trained and employed by the health plan. Six care managers were assigned to the ten sites and were made available by telephone and electronically to their assigned practices, regardless of which office they were in at any particular time. Practice-based care managers provided care management support at the participating sites for certain high-need members with one or more chronic conditions, including diabetes, heart disease, depression, and asthma. Members were
III. Legal/Regulatory Framework

Now that the general framework of a PCMH has been described, there are a number of legal hurdles that must be navigated that will, in part, determine the general structure of the PCMH model. Applicable with PCMH arrangements, parties must consider the federal physician referral prohibition or Stark Law, the federal anti-kickback statute, the civil monetary penalties law ("CMP"), tax, anti-trust, and state physician referral and anti-kickback laws. While the OIG, CMS, FTC and IRS have provided safe harbors with regard to shared savings programs such as ACOs, there are no specific exceptions or safe harbor protections for PCMH models. However,
given that PCMHs have been described as mini-ACOs, the current law pertaining to ACOs is a useful guide for structuring PCMH arrangements.

**Stark Law**

Effective for referrals made after December 31, 1994, if (i) a physician (or an immediate family member of such physician) has (ii) a “financial interest” in an (iii) entity, (iv) the physician may not make a referral to that entity (v) for the furnishing of “designated health services” (vi) for which payment is sought under Medicare or Medicaid, and the entity may not present a claim or bill to any individual, third party payor, or other entity for designated health services. All six of the elements of Stark must be present to implicate the statute. If all six elements are present, the referral will only be protected if an applicable exception applies. There are no safe harbors excluding a referral from the self-referral ban. If a referral arrangement is not specifically excluded by the statute, it is subject to the ban. Stark is violated when DHS services are billed, not when the referral itself is made; thus, the ban is on billing not the referral.

A “financial interest” is broadly defined and includes either an equity interest, including debt, whether directly or indirectly, or a compensation interest with an entity providing DHS (the “DHS entity”). It may be very likely that participating PCMH physicians will enter into some form of agreement with a DHS entity to provide services. Therefore, the structure of the PCMH will need to fit within an applicable Stark exception if the participating physicians are the PCMH have a financial interest in a DHS entity for any DHS services.

The most relevant exceptions with respect to services provided to a DHS entity involve (i) personal services, (ii) indirect compensation, (iii) bona fide employment, and (iv) donation of EMR.

- **Personal Services** – If the structure of the PCMH model contemplates that participating physicians either individually or as members of a group practice will be providing services to a DHS entity and being compensated by the DHS entity for such services, any remuneration received by the referring physician will be exempt if the arrangement meets the following qualifications:7

  - The arrangement is set out in writing, signed by the parties, and specifies the covered services.
  - The arrangement covers all services to be provided by the physician.
  - The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement.
  - The term is for at least one year. Phase II modified the one-year requirement to permit a termination clause (with or without cause); however, if the agreement is terminated within the first year of the original term, the parties are not permitted to enter into another agreement for the same or similar services for the remainder of the first year.

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6 P.L. 103-66, 13562(b)(2).
7 42 U.S.C. § 1395nn(e)(3).
o The compensation is set in advance, does not exceed fair market value,\(^8\) and is not determined in a manner that takes into account the volume of referrals or other business generated between the parties.

o The services to be performed do not involve the counseling or promotion of a business arrangement or other activity that violates any state or federal laws.

o A contract for personal service is permitted a holdover not to exceed 6 months so long as the payment terms remain the same.

- **Indirect Compensation** – The financial relationship may exist either “directly” between the DHS entity and the referring physician or “indirectly,” that is, where other individual(s) or entity(ies) are interposed in a chain of financial relationships, through ownership, investment interest, or compensation arrangement, between the DHS entity and the referring physician. If a financial interest constitutes an indirect compensation interest, the arrangement may qualify for the indirect compensation exception that meets all of the following requirements.\(^9\) Effective December 4, 2007, Phase III regulations introduced a broader “stand in the shoes” (“SITS”) rule for purposes of determining whether a physician has a direct or indirect financial relationship with a DHS entity.\(^10\) Under the new regulations, a physician is deemed to “stand in the shoes” of his or her “physician organization” if the only entity between the referring physician and the DHS entity is the physician's physician organization. In such cases, the referring physician will be deemed to have a direct financial interest with the DHS entity. If a group practice in which a physician has an ownership contract to provide services to a hospital, the relationship between the group and the hospital is a direct financial relationship. For example, where a DHS entity pays fees under a service agreement to an undifferentiated medical group, the fees will be treated as having been paid to each physician. In such cases, the financial arrangement must satisfy an applicable direct compensation exception (e.g., lease, personal services, fair market value, etc.) and not the indirect compensation exception. Note: If the stand-in-the-shoes rules apply to a particular financial arrangement, the indirect compensation exception is not available to protect the arrangement and must rely on a direct compensation exception.

- **Bona Fide Employment** – If the PCMH model is designed so that the participating physicians are employed by the PCMH entity, there is an exception for any amount paid by an employer to a physician (or an immediate family member of such physician) who has a bona fide employment relationship with the employer for identifiable services. The amount must be consistent with fair

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\(^8\) As to fair market value guidance, the preamble suggests that the analysis should first determine what the service could have been bought for in the absence of an arrangement with a referring physician. However, in the absence of reasonable market comparables, the fair market analysis looks at the supplier’s costs plus a reasonable return. Relative to the need to obtain an outside appraisal, the preamble suggests that internal audits are susceptible to manipulation and do not have strong evidentiary value.

\(^9\) 42 C.F.R. § 411.357(p).

market value, not determined in a manner that takes into account the value of any referrals, and commercially reasonable, even if no referrals were made to the employer.\textsuperscript{11}

**Federal Anti-Kickback Statute**

Section 1128B(b) of the Social Security Act, known as the anti-kickback statute (“AKS”), prohibits the offer, solicitation, payment, or receipt of any remuneration, in cash or in kind, in return for, or to induce, the referral of a patient for any service that may be paid by a Federal Healthcare Program (most notably, Medicare and Medicaid).\textsuperscript{12} Prohibited conduct also includes remuneration in return for purchasing, leasing, ordering or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item reimbursed under Medicare or a state health care program. “Remuneration” has been broadly defined to encompass anything of value. The Medicare and Medicaid Patient and Program Protection Act of 1987 required HHS to promulgate regulations specifying and protecting payment practices encompassing legitimate business practices (so-called “safe harbors”) that will not be subject to criminal prosecution, or exclusion from the Medicare and Medicaid as involving prohibited remuneration. If a payment practice fails to comply with any of the promulgated safe harbors, it is not thereby deemed unlawful. However, the payment practice will be measured against the statute, and unlawful remuneration may be found to exist based on the parties’ subjective intentions under the particular facts and circumstances presented.\textsuperscript{13} The most relevant “safe harbors” that may apply to a PCMH arrangement where physicians are in a position to refer business to other individuals or entities is the (i) personal services and management contracts, (ii) bona fide employment, and (iii) donation of EMR contacts.

- **Personal Services and Management Contracts** – The requirements for the AKS safe harbor are very similar to the Stark exception. Payments made by a principal to an agent as compensation for services provided by the agent are covered if the following conditions are satisfied: (1) the agency relationship is set out in writing and signed by the parties; (2) the agreement specifies the services to be provided; (3) the agreement is for a period of not less than one year; (4) the amount of compensation is set in advance and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties that would be subject to reimbursement under the Medicare or Medicaid program; (5) the services do not violate any federal or state law; and (6) the services contracted for do not exceed those that are reasonably necessary to accomplish the commercially reasonable business purpose of the services.\textsuperscript{14}

- **Bona Fide Employment** – Also similar to Stark, remuneration does not include any amount paid by an employer to an employee,\textsuperscript{15} who has a bona fide employment relationship with the employer.\textsuperscript{16} The term “employee” has the same

\textsuperscript{11} 42 U.S.C. § 1395nn(e)(2).
\textsuperscript{12} 42 U.S.C. § 1320a-7(b).
\textsuperscript{13} Id. at 35957.
\textsuperscript{14} 42 CFR §1001.952(d).
\textsuperscript{15} §3121(d)(2).
\textsuperscript{16} 42 CFR §1001.952(l).
meaning for purposes of satisfying the safe harbor as it has for federal employment tax purposes.

**Electronic Health Records**

In many cases, the PCMH will arrange to be the recipient of donated EHR support software. Such remuneration would otherwise implicate both the Stark Law and AKS. Both the OIG and CMS issued regulations providing a safe harbor under the AKS and exception under Stark for donated EHR software. Both regulations require the following requirements to be satisfied to gain protection under the applicable statute, the majority of which are identical, except as set forth below.

1. **Class of Donors and Recipients.** The hospital and recipient physicians must be within the class of donors and recipients identified under each regulation. With regard to the Stark Law Exception, "entities" are permitted to be donors. Under the Stark Law, any entity that furnishes designated health services is an "entity." There are numerous designated health services, including inpatient and outpatient hospital services. With regard to the Anti-Kickback Safe Harbor, a "donor" is permitted to be any individual or entity that provides services covered by a federal health care program and submits claims or requests for payment under that program. With regard to the Stark Law Exception, physicians are the only eligible "recipients" since the Stark Law covers only financial relationships with physicians. With regard to the Anti-Kickback Safe Harbor, eligible "recipients" include any individual or entity engaged in the delivery of health care.

2. **Appropriate Scope of Items and Services.** In order to gain protection under the Exceptions, the items or services donated must be "software or information technology and training services necessary and used predominantly to create, maintain, transmit, or receive electronic health records." Hardware, such as software with core functions other than as an EHR system, e.g., standalone practice management, is not included.

3. **The software must be interoperable.** Software will meet the definition of interoperable if, at the time of donation, the software is able to: (i) communicate and exchange data accurately, effectively, securely and consistently with different information technology systems, software applications and networks and (ii) exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered.

4. **No Limitations on Donation by Hospital.** The donor (or any person on the donor's behalf) may not take any action to limit or restrict the use, compatibility

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or interoperability of donated items or services with other electronic prescribing or EHR systems.

5. **No Conditions on Receipt by Physician.** Both regulations specifically state that neither the recipient nor the recipient's practice (or any affiliated individual or entity) may make the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor.

6. **Eligibility Not Based on Volume/Value of Referrals.** The donor is permitted to select a recipient and/or the nature of the items or services, provided that the factors that are used do not directly take into account the volume or value of referrals or other business generated between the parties, including factors such as, the total number of prescriptions written by the recipient/physician, the size of the recipient/physician’s medical practice, or whether the recipient/physician is a member of the donor’s medical staff.

7. **Written Agreement.** The arrangement must be set forth in a written agreement that: (i) is signed by the parties; (ii) specifies the items and services being provided, the donor's cost of those items and services and the amount of the recipient's contribution; and (iii) covers all of the EHR items and services to be provided by the donor (or any affiliate).

8. **Knowledge of Equivalent Items or Services.** The donor must not have actual knowledge, act in reckless disregard, or deliberate ignorance, of the fact that the recipient possesses or has obtained items or services equivalent to those provided by the donor.

9. **No Patient Restrictions.** The regulations require that the items or services donated can be used for any patient without regard to payor status and prohibit the donor from restricting or taking any action to limit the recipient's right or ability to use the items or services for any patient.

10. **Staffing/Relation to Clinical Operations.** The regulations specifically prohibit the donor from contributing physician office staff or assistance in converting paper medical files to electronic medical records as part of the implementation process.

11. **E-Prescribing Capabilities.** Donated EHR software must contain an electronic prescribing capability either through an electronic prescribing component or the ability to interface with the recipient's existing electronic prescribing system.

12. **Cost Sharing.** Before receipt of the items and services, the recipient must pay not less than 15% of the donor's cost for the items and services qualifying for the donation.
Civil Monetary Penalties (“CMP”)

Effective PCMHs provide care in a manner that is not only intended to improve quality outcomes and patient satisfaction, but also reduce costs to both the patient and the federal government. However, PCMHs need to be careful when working in tandem with hospitals to coordinate cost saving measures or if they engage marketing strategies that provides some form of remuneration to Medicare beneficiaries as an inducement for their business. Specifically, CMPs may be imposed for conduct that involves (i) payments by a hospital to a physician, directly or indirectly, as an inducement to reduce or limit services provided to Medicare/Medicare beneficiaries,18 or (ii) offering to or transferring remuneration to any Medicare/Medicare beneficiary by a person who knows or should know is likely to influence such individual to order or receive items or services payable, in whole or in part, by a federal healthcare program (e.g., Medicare or Medicaid).19 If shared savings are paid by the PCMH then the CMP law may be implicated and, as mentioned above, there are no “waivers” or other exceptions that specifically apply to PCMHs as they do to ACO, but because of many similarities, those waivers should be referred to as guidance when structuring any shared savings or gainsharing arrangement.

Federal Income Tax Exemption

If the PCMH is structured to qualify for federal tax exemption as an organization described in I.R.C. §501(c)(3), the IRS will carefully scrutinize the arrangement to make sure that the organization is organized and operated primarily to benefit the public and not the individual participating physicians and that no part of the net earnings of the organization inure to the benefit of any private shareholder or individual (a so-called “insider”).20

Anti-Trust Laws

The combination of primary care providers under a PCMH model or network potentially unites into one entity potential competitors. Without significant financial or clinical integration, the PCMH may violate the Sherman Act and Federal Trade Commission Act.21 The Federal Trade Commission published a proposed safe harbor for ACOs that should be referred to as guidance given the similarities of these two models.

IV. Examples of Beneficial Uses of PCMH

About an hour’s drive east of Philadelphia, AtlantiCare Health System (“AtlantiCare”) is South Jersey based with locations in Atlantic City, New Jersey and the surrounding communities along the Jersey Shore. The primary and secondary service areas are approximately 400,000 in population with 35 million people visiting the resort city every year. Despite the image of sandy beaches and glitzy Casinos, 30.29% percent of the 40,517 residents of Atlantic City and 21.20%
percent of the 17,907 residents of neighboring Pleasantville live below the poverty line.\textsuperscript{22}

AtlantiCare’s two (2) acute care hospitals provided approximately $50 Million in free care at their cost in 2012 and only received approximately $25 Million in charity care reimbursement from the State of New Jersey.\textsuperscript{23}

Much of AtlantiCare’s success is related to the commitment to innovation and quality in fulfilling AtlantiCare’s mission of delivering “health and healing to all people through trusting relationships” and the vision of “building healthy communities”.\textsuperscript{24} Breakthroughs include the creation of the AtlantiCare ACO based on a network of employed and independent physicians and allied health providers organized in PCMHs and the development of a multidisciplinary clinic model for chronically ill patients, called the Special Care Center (SCC), a group model PCMH. In addressing the needs of stakeholders in the community, through integrated, team based care via the ACO provider network, the ACO achieved a decrease in A1C levels in the blood tests of diabetics through a process of implementing a diabetes care management program in 2012. With a benchmark against the national average of 8.3\% of the American population having elevated A1C levels, the AtlantiCare primary care practices served a population where 9.8\% of had elevated A1C levels.\textsuperscript{25} By adopting a diabetes care management program that utilizes the resources of its primary care physicians who achieved PCMH status working in conjunction with endocrinologists and the Joselyn Diabetes Center, the AtlantiCare ACO was able to reduce the percentage of patients with elevated A1C to 7.7\%.\textsuperscript{26} Such innovations in health care practice are another attraction for physicians in joining the AtlantiCare ACO.

Prior to the establishment of the ACO, AtlantiCare redesigned care in a change management project by integrating the care of Casino employees and union members with chronic diseases such as congestive heart failure, diabetes and obesity into one location in downtown Atlantic City in a group model PCMH, the Special Care Center. Through the collaboration of a care team including an assigned primary care physician, pharmacist, dietician and health coach, the SCC has provided value to its patients by decreasing emergency department visits by 40\%, surgeries by 20\% and overall healthcare costs by 25\%.\textsuperscript{27} Such efforts have led to financial stability and awards and designations including the Malcom Baldrige Quality Award in 2009 and Magnet status for excellence in nursing.

In addition to improving healthcare outcomes such as diabetic, congestive heart failure and obesity, PCMH and MU designation also provides other values to physician practices. For example, AtlantiCare has implemented an insurance purchasing alliance for reduced malpractice insurance for those physicians participating in the ACO. Participating ACO physicians have to achieve certain requirements including the provision of care in a PCMH model, in addition to the meaningful use of EHR. With these additional requirements leading to improved quality,

\textsuperscript{22} http://zipatlas.com/us/nj/city-comparison/population-below-poverty-level.htm
\textsuperscript{23} http://www.njha.com/media/54819/2012_CharityCare_Model.pdf
\textsuperscript{24} AtlantiCare Strategy Map, 2013
\textsuperscript{25} Transformation Care Application for 2012 AtlantiCare Team Award
\textsuperscript{26} Id.
\textsuperscript{27} Gawande, A., “The Hotspotters”, The New Yorker, January 24, 2011, pp. 46-
malpractice carriers are willing to provide reduced premiums. Such incentives reward physicians for improved quality further motivating improvements in care.

The above are just a few examples of using PCMH and MU to the benefit of patients, providers and payors. These examples will only grow as healthcare reform is further embraced and innovative models of care and programs are developed. As building blocks for the next generation of care, physician practices and the attorneys and consultants supporting them should take notice because change is upon us now.