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NAMCP MEDICAL DIRECTORS GUIDE: ONCOLOGY

The Oncology Landscape: How Oncology Trends and Management Challenges Will Affect Medical Directors of Plans, Purchasers and Providers, and NAMCP Strategies to Address These Issues

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TABLE OF CONTENTS

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The Oncology Landscape: How Oncology Trends and Management Challenges Will Affect Medical Directors of Plans, Purchasers and Providers, and NAMCP Strategies to Address These Issues

Dawn Holcombe, MBA, FACMPE, ACHE

Summary

The mission of the Medical Directors Oncology Institute of the National Association of Managed Care Physicians (NAMCP) is to open the lines of communication between medical directors in managed care and practicing oncologists to help them jointly better navigate and understand what is happening in managed care and the day to day management and practice of oncology. This guide presents an overview of the business of oncology, as well as the challenges and issues for physicians and oncology management challenges from the health plan perspective. It discusses oncology management in the context of the business of oncology, and issues and strategy for plans and purchasers seeking solutions for oncology management. The guide presents activities and initiatives within the NAMCP Oncology Institute to support medical directors from plans, purchasers and providers, and to eventually achieve greater collaboration that should lead to improved patient outcomes in oncology.

Introduction

This Medical Directors Guide from the National Association of Managed Care Physicians (NAMCP) reviews the current state of the business of oncology and addresses developing non-clinical issues related to the management of oncology. Oncology treatment and costs are among the top concerns for health plans and purchasers, yet most medical directors in those venues are not oncology-trained specialists. There is great interest and increased discussion about the management of oncology, but too often plans and purchasers are also seeking a context in which to evaluate potential oncology programs. Many oncology vendors and physicians have started to approach medical directors on a regular basis. Members of NAMCP have asked for assistance and support from NAMCP in terms of a context in which to consider oncology management options, to take a look at the resources that NAMCP can offer, and to develop oncology policy strategy.

Health Plan Considerations for Oncology Policy

Most medical directors for health plans and employers are not medical oncologists. Although very concerned about costs and policy issues for cancer, they are not always certain of what questions to ask and where some of the less obvious issues lie. This guide reviews common concerns and issues that medical directors might want to address when embarking upon a policy for oncology. Questions actually asked by medical directors, expressing where they felt that further information would be helpful, are also included.

Common Concerns for Medical Directors Building Oncology Strategy

Medical directors have many concerns about building an oncology management strategy. Commonly asked questions that have been brought up by NAMCP members and other medical directors include:

1. Understanding Oncology – What are the hot

issues and trends that could affect care and policy?
2. Oncology delivery and management models – How to distinguish between different programs, and how to consider what might be the impact (on the plan, physicians or patients) of choosing one versus another?
3. Oncology programs – Who is doing what?
4. How do I define quality or value? Why do quality measures now used in oncology seem to focus more on process of care than outcomes? What does "value" mean to different stakeholders?
5. Oncology quality – who, how, what, where
   a. "Evidence" definition and acceptance
6. Costs of drugs – How would different policies impact costs?
7. Costs of care – and access to care – How would different policies impact costs or patient access to care?
8. Relationships with physicians
   a. Negotiations/collaborations – current examples of effective and ineffective
   b. How to start dialog (i.e., Physician groups might start with provider reps at plans rather than medical directors, or medical directors might be cautious about starting a discussion with physicians that is too far removed from traditional contracting discussions.)
   c. What data to look at and when?

Topics and Questions Raised by Medical Directors

The following are topics and questions commonly raised by medical directors of plans and purchasers regarding oncology:

- How do I define costs in oncology and what are the key variable points? How are oncology costs being managed and by whom?
- What is the impact of oral drugs in oncology management?
- What are the key considerations for specialty pharmacy roles in oncology, and drug sourcing from physician inventory or shipped drugs to physicians?
- What is the impact on health plans and their en rollees of different delivery models like physician or hospital-based, retail infusion centers, Accountable Care Organization (ACO) or medical homes?
- What is 340B and how might it affect oncology in my market?
- What questions might be useful regarding site of service?
- Does the timing of care review and authorization affect patient care access?
- What is "evidence-based" care and are how might different perspectives vary from managed care concerns?
- Could some benefit structure changes cause in advertent shifts that will result in higher over all care costs?

These questions are all factoring into choices, within a cancer center or a health plan, that are being made about the management of oncology that affect the cost, quality and access of cancer care. In these choices, it is useful to be aware of the many variables involved, while building a uniquely filled toolbox about how oncology care will be managed. NAMCP is developing tools and support for the decision-making challenges that face their members.

Key Oncology History Affecting Policy Today

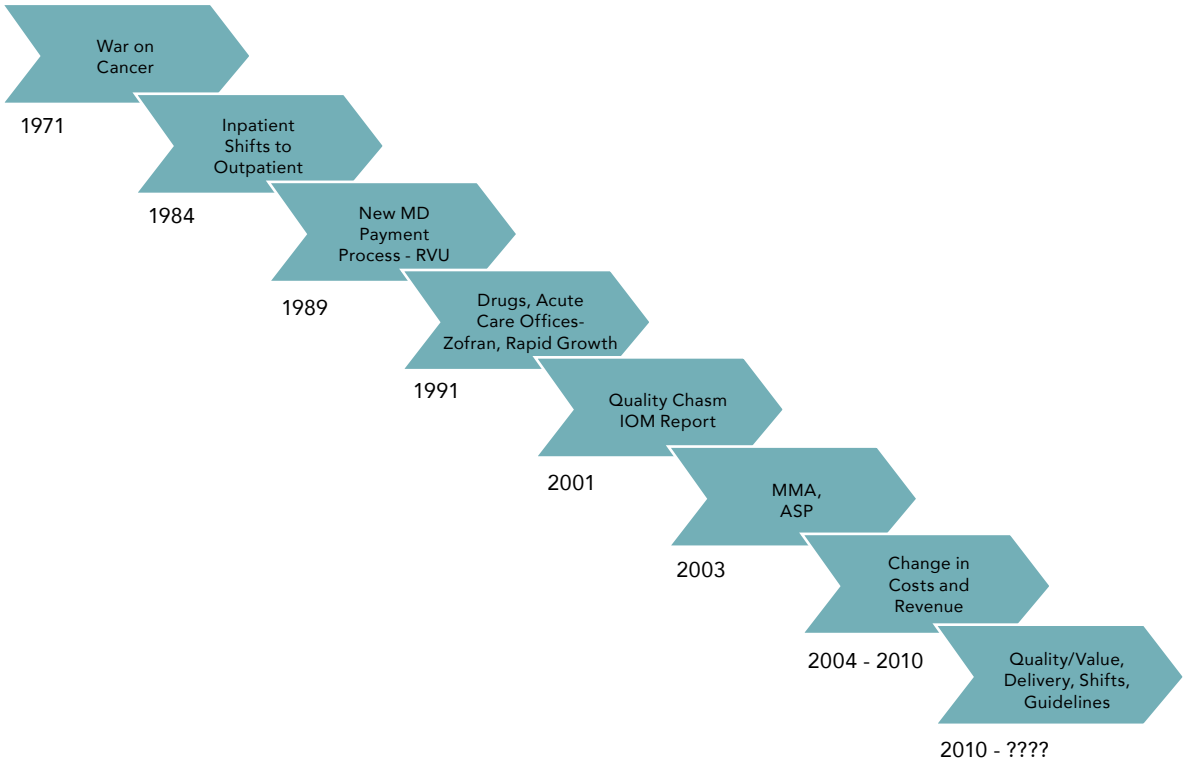
Oncology is not a conventional physician office service. Most care is delivered in sophisticated private physician offices, which combine complex chemotherapy infusions with physician evaluation and treatment. Most are in a hospital building or cancer center, with the private physician office practicing in rented space adjacent to a hospital-based imaging or other oncology facility. To the outside person, this may look like a full hospital-based cancer center, and some might not realize that the medical oncology physicians are a private practice independent of the hospital. It is common to see medical and infusion services together, with or without imaging. However, the delivery models for oncology are in flux. Federal reform has dramatically changed the financials of physician and hospital-based oncology, with significant resultant impact and import for NAMCP members. Physician practices are being acquired in record numbers by hospitals. External interest in oncology is growing. Questions about evidence and outcomes are sometimes outstripping the existing technology curve.

Journey of the Business of Oncology

This review of the history of the business of oncology (Exhibit 1) will offer perspective when developing policy on oncology opportunities and challenges, whether you are a medical director of a health plan, employer, or health system.

President Nixon declared the War on Cancer in 1971. Millions of dollars moved into research for cancer treatment and drugs. However, cancer was a hospital-based disease (popularly reflected in the movies "Brian's Song" and "Love Story") because of the toxicity of the drugs. In 1984, the Diagnosis Related Group (DRG) system was implemented as a

Exhibit 1: Journey of the Business of Oncology



new way of bundling services in the hospital setting. Established prices were low for the inpatient chemotherapy DRG, thus moving much of what had been inpatient cancer care into the hospital outpatient setting. Limitations in medical and clinical management of oncology treatment and side effects initially kept most care in the hospital outpatient setting – physician offices wouldn't become a primary care site for another five to six years.

However, in the late 1980s, a new payment process for all physicians was developed called the Resource Based Relative Value System (RBRVS). The RBRVS values and rates were set after lengthy review and studies of workflow in MD practices. Unfortunately, this was many years before 1991, when Zofran was approved by the FDA and became one of the first of many drugs that made it possible to actually manage oncology in the physician office. It wasn't until the early 1990s that oncology trained physicians and nurses evolved the practical practice model for cancer evaluation and infusion treatment in the office setting that quickly became the norm for most cancer care delivered in the United States. Therefore, the RBRVS rates have not, from their inception, accurately reflected the professional services and overhead of a present day oncology practice.

From the very beginning, the RBRVS payment structure created an imbalance related to the work effort and the professional services for oncology that never actually caught up to reality. In the interim, the government created a reimbursement methodology for drugs based on Average Wholesale Price (AWP) – which was widely understood to include margins that were used to offset the growing gap caused by under-reimbursement of professional services. But as new drugs came on the market and drug prices continued to rise, use of the AWP model as a bandage for covering both drug and office costs became unsustainable.

By 2004, the Medicare Modernization Act (MMA) had passed, which, in part, changed the federal reimbursement for drugs to the Average Selling Price (ASP) model. There was a provision in the MMA to correct the weaknesses related to oncology physician services codes, but those adjustments were never actually enacted in the year allowed for the correction. Oncology practices saw an immediate decline in revenues and rapidly retooled operations and care management to adjust. Medicare reimbursement for both drugs and professional services continued to decline, making net reimbursement of the costs to treat Medicare patients a break-even proposition for cancer practices – and frequently a net loss. More recently, concerns about

the fee for service system in general and continuity of care have led to a push for payment reform on the public and private fronts, and physicians and plans each are struggling with workable alternatives.

The federal government approved in 1992 a new program intended to support hospitals that were taking care of a comparatively large number of indigent patients as opposed to other hospitals in the country.[1] A "disproportionate share hospital (DSH)" could apply, and upon proving that all the sites on its recent Medicare cost report cared for a market mix of at least 11.75 percent of eligible category patients (in total), could qualify for a special drug pricing program for all outpatient drugs purchased for use at the hospital and its related approved sites. These drug prices (known as the 340B program) represent a substantial discount over market drug prices, and are intended to allow the hospital to use the savings to stretch its resources so that it can increase patient services with the savings. Not all hospitals qualify, and those that do must recertify every year. With ongoing mergers and acquisitions, it would not be uncommon for a new system to include both eligible and non-eligible hospitals. Eligible hospitals must enroll by one of four quarterly deadlines, and sites within that entity are not eligible until they have been reflected on the hospital's most recent Medicare cost report and approved into the program – a process that can take several months – and often as many as 18 months. Covered entities are not allowed to divert the 340B drug to non-approved sites, to patients not under treatment at their covered facilities, or for inpatient drug use.

There has been some concern expressed that hospitals may be using some of the 340B savings to create an attractive offer for acquiring private oncology practices. Hospitals might counter that the program is intended to allow them to cover their DSH eligible patients and to extend services – as well as note that physician practice acquisition is part of a strategic plan to support Accountable Care Organization (ACO) development for their patient market. Since 340B covered entities must purchase all outpatient drugs under the program as a condition of participation, some private payers have expressed concern that commercially negotiated rates for those hospitals might leave significant margins in the hospital's hands. The program itself is under review, and there are active audits and even Congressional inquiries into the appropriate management and qualification of 340B program entities. At this point in time, the program is continuing to operate as originally planned, and, if there are any corrections to be made, individually or universally, they will likely follow the outcomes of the audits and inquiries.

Example of Oncology History and Complexity – Lung Cancer

While every cancer is different, lung cancer can be used as a general example of how cancer treatment has evolved. Lung cancer is considered one of the "top 4" cancers, diagnosed in over 226,000 Americans each year.[2] But lung cancer is not actually one cancer; it encompasses two major types of lung cancer: non-small cell lung cancer and small cell lung cancer. Yet even these designations are not sufficient. Non-small cell lung cancer accounts for close to 85 percent of all lung cancers, but it includes different types of tumors (each of which are treated differently). Some non-small cell lung cancer tumor types include adenocarcinoma, squamous cell carcinoma and large cell carcinoma (non-small cell lung cancers that are neither of the other two types). Small cell lung cancers account for the other 15 percent of diagnosed lung cancers in the United States.

Each of these tumor types can present in different stages (stage I, II, III, IV or limited or extensive) and different parts of the body. Some tumors are more responsive to chemotherapy than others. Because the lungs are a fairly large organ in the body, tumors can grow for a long time before they are discovered – leading to mostly late stage diagnoses (stage III and IV). Even with screening, these cancers can be difficult to detect.

New developments have identified proteins or molecules that can provide a better understanding of an individual tumor. These are called biomarkers because they exist in or on the tumor cells. Physicians can now test for lung cancer biomarkers such as epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK) or K-ras mutations (KRAS). Presence or absence of the biomarkers can help physicians make decisions regarding treatment options.

Treatment for the various lung cancer tumors can vary from surgery, radiation, chemotherapy or targeted treatments and any or all of these may be appropriate for the specific tumor. Targeted therapies that attack specific cancer cells are the latest evolution in treatment. Most often these targeted therapies show value either in conjunction with traditional chemotherapy or following failure of traditional chemotherapy. Targeted therapies may be a higher cost than traditional therapies, and may also include the costs of testing - but may yield more success with the specific targeted tumors than a more broad-spectrum chemotherapy option. Clinical trials always remain a solid clinical alternative for treatment – but are more likely to be found for patients who have failed earlier treatments – or whose disease has

already progressed to later stages. When there is an accepted standard of care with strong clinical evidence for success (as is the case with many adjuvant cancers), ethical concerns would negate the provision of an unknown clinical trial option for patients with known possible positive alternatives – hence most clinical trials for new treatments are focused on patients with few other alternatives – usually in metastatic or advanced disease.

This review of the complexity of lung cancer illustrates the difficulty that health plans, physicians and even patients have in managing cancer. Current screening methods, may not yield more early diagnoses. The term "lung cancer" (as is the case for every broad descriptor of "cancer") is seen to be actually a loose label for several very diverse tumors – each of which has different triggers, responses, and patterns of progression from the others. Treatment choices are not simple, and may vary widely depending upon the specific type of lung cancer tumor involved. Many details and variables are involved in the treatment decision process, and most of those variables do not make it into claims processing transactions, or even many prior approval processes. These gaps in information can make it difficult for health plans, physicians, and other external entities, to always have sufficient information at hand for determining appropriateness of treatment. Guidelines or pathways may have challenges in reflecting the broad range of diagnostic and clinical variations between specific tumors – let alone staying current on new information.

Oncology Delivery Today

Today in oncology, between one half and three quarters of patients receive their cancer treatment in physician owned community oncology offices: these settings more resemble acute care centers than the common exam room based physician office. Patients are evaluated by a physician with supporting diagnostics and imaging resources, and then, if treatment is indicated, are cared for in a full service infusion center, which is usually part of the office. Cancer drugs are intended to kill human cells at the most basic level. Medication toxicities can and do present on a sudden and regular basis. Highly trained and skilled oncology physicians and nurses monitor the patient through their treatment. Because much cancer is evolving into a chronic disease rather than automatically fatal, survivorship management is as important as the still inevitable palliative and end of life management. Patient health status and response to treatment are assessed constantly, before and during every treatment event.

A typical private oncology office houses a broad range of services. Some of the services could include lab and other diagnostics, clinical trials, palliative care, diet, nutrition, social and supportive services counseling, peer support, and financial counselors, among others. Many of these services are not reimbursable, but are provided because of their value to quality cancer care. Depending on local and state regulations, practices will also provide imaging, radiation oncology and pharmaceutical dispensing in these private offices. Regulatory requirements are the primary reason why some private offices provide specific services, or dispense oral medications, and others do not. For example, in the state of CT, no private oncology office does imaging because of the Certificate of Need (CON) status for such equipment in the state. Very few physicians in CT dispense oral drugs because of the pharmacy regulatory requirements within the state. In other states, practices will dispense oral cancer drugs (typically not as a strong revenue stream, but as a way of assuring continuity of care and clinical oversight for their patients.)

Other oncology care delivery settings include hospital cancer centers, specialty cancer hospitals, and National Cancer Institute (NCI) designated cancer centers and comprehensive cancer centers. There is very little utilization of home infusion services for cancer treatments, due primarily to the risk and toxicity of the treatments and medical oversight requirements.

Hospital cancer centers may be in free standing or dedicated medical office space. The physician services may be delivered by those fully employed by the hospital or combination of hospital-employed physicians and private practice physicians who are renting space in the cancer center for the benefit of patients to receive coordinated proximate care for their diagnostic, medical, imaging and radiation oncology services. Specialty cancer hospitals may be for profit, like Cancer Treatment Centers or America, or not for profit, and are not found in large numbers across the United States.

NCI designated centers receive significant research funding. There are 26 NCI designated Cancer Centers in the United States, each of which has a scientific agenda that is primarily focused on laboratory, population science, or clinical research, or some combination of these three components. There are 44 Comprehensive Cancer Centers that demonstrate depth in laboratory, clinical, and population-based research, with substantial transdisciplinary research in all three areas. These institutions also provide professional and public education, as well as dissemination of clinical and public health advances into the communities they serve. The National Comprehensive Cancer Network®

(NCCN) is a not-for-profit alliance of 21 of the world's leading cancer centers, all of which are also NCI designated centers.

Oncology – Key Names and Resources

The following are key associations involved in the clinical and operational management of oncology. These are all membership-based organizations, and most have developed essential clinical tools and resources, as well as practice management and coding resources for private and hospital-based oncology physicians.

- The American Society for Clinical Oncology (ASCO), www.asco.org
- The National Comprehensive Cancer Network (NCCN®), www.nccn.org
- The Association of Community Cancer Centers (ACCC), www.accc-cancer.org
- The Community Oncology Alliance (COA) www.communityoncology.org
- The Oncology Nursing Society (ONS) www.ons.org

There are also networks of practicing oncologists across the country: the Mckesson Specialty Health (McKesson)/US Oncology Network, the Cancer Centers of Excellence, and the Cancer Clinics of Excellence. Almost every state has its own professional oncology association, and may also have a statewide association for oncology practice managers, possibly aligned closely with each other or part of the physicians' association. These networks are growing in their ability to be able to deal with some discussions on a collaborative basis with health plans and employers, on a regional or statewide basis, that perhaps will make it easier to accomplish some of these changes, as opposed to addressing multiple discussions on an individual practice or hospital basis.

The National Business Group on Health (www.businessgrouphealth.org) has partnered with NCCN to build toolkits for business on benefit design related to cancer (http://www.businessgrouphealth.org/resources/topics/cancer.cfm).

There have historically been three primary drug distributors for clinical providers in oncology (Amerisource Bergen, McKesson, and US Oncology (now part of McKesson). Most oncology drugs that are delivered to hospitals or physicians come only from these vendors or other vendors associated with a hospital buying group (like Innovatix or Premier). The majority of cancer care is delivered through injectable and infused treatments. Specialty pharmacy is not commonly used as a primary drug distribution source by oncologists. The distributors that providers use as sources have made a niche business of understanding and addressing the unique needs of the oncology market. Some oncology drugs, primarily orals, are delivered to patients through specialty pharmacies – predominantly drugs that manufacturers have isolated to delivery through limited distribution networks, or drugs that may have been mandated for acquisition through a specialty pharmacy by the health plan.

Some of the other external vendors entering the oncology market space through disease, utilization or drug management include Avalere (Quality Oncology), Magellan (ICORE), US Oncology (Innovent, which focuses on Level 1 Pathways), D3 Oncology Solutions (a guidelines/pathways program from the University of Pittsburgh Medical Center), ITA Training Partners (eviti – a commercial guidelines program), McKesson, (Value Pathways powered by NCCN – licensed decision-making algorithm incorporating the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines™) and New Century Health (licensed to incorporate NCCN Compendium in their program). Specialty pharmacy includes numerous vendors (CVS/Caremark, Walgreens, for example) seeking new roles within the oncology drug management market.

Federal Policy – What It Means for Health Plans Regarding Oncology

It used to be that Medicare was a viable source for oncology policy for the private sector, but its value as a role model and source has lessened because of recent Medicare policies, rates for drug ASPs and professional services rates/codes. In addition to coding and reimbursement changes that have affected oncology policy, Medicare-based discussions of quality measures and programs often fail to address questions and measures that might be considered in the private sector. Demonstration projects that seem to hold promise for inspiring innovation are hamstrung by fine print limitations that, for example, cap Medicare payments at current levels. Since Medicare evaluates such payment in silos for Medicare Part B (outpatient and physicians services) and Medicare Part A (inpatient) care separately, any innovation that seeks higher outpatient payments for care management will be hard pressed to result in significant savings if inpatient care costs are not considered.

Significant Medicare and federal government activity about the Sustained Growth Rate (SGR), the federal debt ceiling, and many political decisions will likely result in changes and reductions in reimbursement that are unrelated to the cost of providing care. When Medicare makes a reimbursement reduction for physician offices, care is frequently shifted over to the hospital outpatient setting, which is

usually more costly due to higher overhead and different contracting options. Medicare doesn't appear to recognize those related consequences that lead to higher overall cost, but payers in the private sector do understand that the hospital site of service is usually more costly than the private physician offices. Many of the Medicare rates paid for oncology drugs and services are now at breakeven or lower, which makes it difficult for physician practices to continue to treat Medicare patients in their own offices. The bottom line is that Medicare policies and payments, while well publicized and easy to find, are not useful for private payers to use as a working model for oncology policy.

Implications of Federal Changes

A number of new delivery models are emerging as a direct result of federal reimbursement policy changes since the passage of the MMA. Private physicians are starting to question if they are going to continue to provide full professional services as well as infusion services. Hospitals are now investing in active cancer outpatient programs, from which many had divested in the past. Academic centers are expanding and creating new employment of formerly private oncologists and even absorbing formerly private offices. Questions are arising about corporate infusion clinics and regional centers. Every single one of those models has a different impact on the patients, physicians and payers, as well as on the quality and the costs of care delivery.

Key Considerations In Developing Oncology Policy

There are many issues about oncology that will affect oncology policy decisions, yet there are are a few core elements which are best considered when embarking upon a policy choice.

1. Keep Perspective Differences in Perspective to Facilitate Communications

Differences in perspective contribute to the challenges of finding solutions. Health plan perspectives often are focused on: the population for which they are responsible and the overall budget, trying to reduce variation and costs in care, needing to improve predictability and to feel confident that they are working with good business partners who will be good stewards of the monies being paid for cancer care. Physician providers are more focused on the individual needing care in front of them, trying to provide patients with help and hope, intending to follow evidence-based care and decision-making but they also are small businesses and want to stay in business. Hospital and academic centers are trying to balance the clinical and treatment needs of the community with the research and education demands of the future for cancer care. Recognizing such differences and listening to the concerns of each other is the first step to identifying win-win solutions. Some vendors who seek to provide oncology management solutions to health plans may have varying degrees of understanding of the complexity of the oncology treatment process, which may open doors or create barriers with treating providers during implementation.

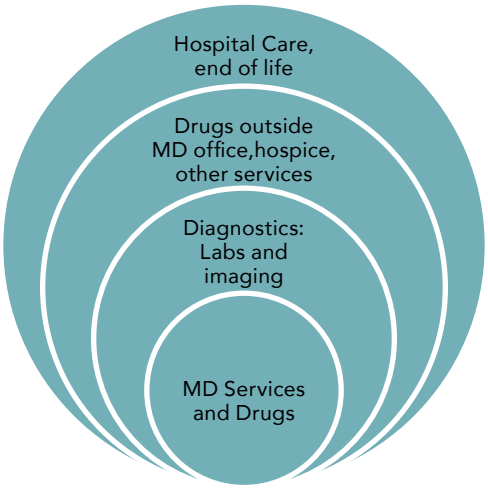
For example, oncology physicians in record numbers are worried about the financial viability of their practices, driven mostly by federal payment reform. Physician practices have mostly embraced the concept that drugs as part of an oncology practice should be cost neutral, not profitable, but also not losing money – particularly on the real costs of acquisition and inventory management – outside of drug administration. One universal problem is that the federal ASP definition of drug cost does not include the costs to acquire the drug, store it, refrigerate and maintain it, and to inventory and replace it once used. Physicians have expressed this concern to private payers. Many private payers have listened and have chosen to follow reimbursement rates that are higher than Medicare's ASP +6 percent, because they do recognize those additional direct and indirect costs. Where is the win for the health plan? Physician practices inherently can deliver care at a lower net cost than hospital-based cancer centers. Oncology policy that keeps practices open and not sold to hospitals, could possibly keep down overall costs for health plans.

2. It's Not About the Drugs … At Least not JUST the Drugs.

Drugs are an easy target when looking at oncology management because they are readily identifiable and billed separately, whether under the medical or pharmacy benefit. However, the biggest component of cancer costs is not actually the drugs used in treatment, but other cancer costs that are driven by medical decision-making. Usually about 20 to 25 percent of the spend for a payer is on professional services and drugs in the office, and the rest falls into a much larger bucket including imaging, hospitalization, end of life, diagnostics and radiation oncology (Exhibit 2).

Most of the oncology management pilots and programs started at health plans in recent years were focused solely on management of the drug and the drug cost, with either a negligible or negative impact on the other costs of cancer. It is easy to engage an external vendor to manage and oversee drugs without any physician involvement but this leaves

Exhibit 2



the health plan with limited opportunities to then reach out to physicians for collaborations that affect the other 80 percent of the cancer spend. For example, a Medicaid drug management decision to solely endorse one product with a lower price net of rebates on paper than another drug, while failing to recognize that the high priced drug could be administered in one shot versus the other's requirements of 10 consecutive daily shots. For a large number of patients, including this Medicaid population, the single shot had the highest likelihood of compliance and thus complete planned effectiveness. The cost of uncompleted treatments and doses of the "preferred" drug would quickly outweigh the comparative price savings, and would adversely affect the care of those patients

It is often so easy to focus on drug spend because the questions related to medical decision-making in oncology are more complicated than comparing prices on Drug A versus Drug B. Most of the clinical details that are needed to understand medical decision-making are in the patient record and do not flow through the claims administration process. Medical treatment decisions are driven by clinical aspects of care such as cancer or disease stage and patient performance status - even patient work and transportation issues Plans usually have no access to those records and no way to track or categorize even the little information they collect during prior authorization processes. Drugs are usually billed from the physician office by J-Codes or by NDC codes if under the pharmaceutical benefit. These can be tracked and monitored for acceptable diagnoses

However, when oncology management has expanded beyond attention just to drug spend, physician engagement, support and participation will be essential to any program that addresses the total cost of cancer, even when many of the dollars involved are not directly or indirectly under their control. Outsourcing solutions from vendors who are not well supported by treating physicians could add costly layers and barriers, rather than moving toward cost effective results.

3. Timing, for Cancer Patients, is Everything

Cancer treatment regimens usually run on fixed cycles of treatment. Once a treatment is started, interruptions in the treatment cycle can jeopardize the value of the treatment itself for the patient, and those funding the treatment. Since many treatments are multiple combinations of anti-neoplastic drugs and supportive care drugs, variations in how the drugs are obtained can cause issues. Health plans can maximize the value of their treatment dollars by ensuring that the review and authorization processes do not interrupt or jeopardize continuation of a treatment once a cycle begins. Delays in authorization processes and extended medical review can exacerbate stress levels in patients already facing a significant health battle. Streamlining the communications between plans and treating physicians can avoid delays or interruptions in treatment and should prove to be very cost effective for patients, physicians and plans.

4. Even in 2012, the Right Data are Elusive

Data challenges in oncology make it very difficult to have a productive collaborative discussion between plans and physicians. Hospital systems, designed for

multi specialty organizations, usually do not have an adequate module designed to capture the unique needs of this specialty (such as clinical trials, NCCN or any key guideline concordance, pathways, drug inventory and management, chair management and tracking). Electronic Medical Records (EMR) are not yet fully implemented in medical oncology. Even oncology specific EMRs often do not, out of the box, collect much of the data that are desired.

Health plans find that their own claims data is inadequate. Claims data, for example, does not give a true picture of whether a particular treatment is primary versus adjuvant care, or how the care correlates with national guidelines for oncology.

This means expectations should be set appropriately for the data available now, and for data needs to be planned for next year and beyond. Another caution would be related to sharing of data. Win/win strategies in oncology will involve sharing of data between plans and treating physicians. In order to be effective, plan-based programs that collect clinical data from physicians must provide useful, from the physician's perspective, assessment of practice trends back to the participating physicians. Truly effective programs will find ways to integrate physician derived clinical information with total cancer cost information from the plans for both individuals and populations; thus both plans and physicians can assess and develop future strategies from mutually accepted analytics. Pilots involving such data sharing and plan/physician collaboration have been started in recent years, and are likely to continue to increase in the future.

5. Process Trumps Outcomes, For Now

With increasing focus on pay for performance, and quality measures in other specialties and diseases, the next obvious question is what outcomes define quality in oncology. The problem is that cancer is unique to each individual, and most cancer care is provided in diverse smaller groups of private practice groups. Pay for Quality initiatives have been more successfully applied in other diseases where timing of the treatment, patient dynamics, and other variables are fairly tightly controlled. Those tight parameters are less applicable when dealing with cancer.

National oncology guidelines with levels of consensus and evidence do exist, but the individuality of the patient, the disease and the physician, coupled with the lack of aggregated data on actual treatments chosen for large populations of cancer patients mean that it may not be possible to understand fully how cancer care will play out for an individual patient. It will be difficult to define quality or outcomes until sufficient current practice treatment patterns are collected in a consistent manner with consistent application of mutually acceptable treatment parameters. There are pilots and isolated oncology data and registry collection programs scattered across the country, which may lead to a focused, scale-able national registry in the future, including one program using IBM's Watson computer and several key health plans and providers.[3]

ASCO created a Quality Oncology Practice Initiative (QOPI) to help practices conduct chart reviews twice a year, and report findings into a central database. This database returns information to the individual practice across over 70 measures – measures that assess levels of documentation, patient support and education, treatment assessment, clinical decision-making and validation, among others. These measures of essential elements to the process of quality care are reported solely to the practice as a means of continuous quality improvement. Some health plans have decided to support, through payments and incentives, those practices that choose to achieve QOPI certification. The variation of process found among practices who participate indicates that, at this stage of quality assessment for cancer care, the most measureable elements will be related to consistent process in delivering care and in complete decision-making, rather than focusing on the clinical results for patients. More than 100 oncology practices nationwide have achieved QOPI certification, so this is becoming one very useful early indicator of quality and thoughtful medical decision-making for plan and employer assessment.

ASCO has also recently received national funding and finalized key data agreements for ASCO's CancerLinQ (Learning Intelligence Network for Quality). It is now conducting early models for a system to connect oncology practices, measure quality and performance, and provide physicians with decision support in real time.[4]

6. Oncology Management Models – Provider or External Vendor

Oncology management is a loose description that can apply to the management of the patient and the disease performed at the provider level, or, on a more broad scope, the application of policies and decisions that shape both the treatment decisions, the benefit structure, and the ultimate dollars and resources expended for the treatment of cancer across a broad population – i.e., at the health plan level. Differences in perspectives regarding individual patient management and management of a broad population can lead to confusion and disagreement in the absence of good communication between health plans and providers. Clarity and transparency of policy and evidence will

more likely lead to agreement and collaboration.

Physician led initiatives to manage oncology are growing, mostly through the development of treatment guidelines or clinical pathways. Some of these clinical guidelines and pathways are available commercially; others may be developed internally. The process of creating, maintaining, and implementing clinical management is costly in terms of both human and technological resources. Some physician groups or cancer centers may wish to approach health plans regarding new payment models that reflect recognition of the more intense medical decision-making and reporting, or other solutions such as evidence-based and value driven structures. Oncology medical homes will be a growing topic for discussion initiated by oncology providers.

Health plans may also be developing internal or seeking external support for better understanding and management of the oncology care spend. Some models may be limited to drug management, some may or may not engage the care providers in active involvement in the program, and some may be simple technological processes through which providers will need to process treatment requests. Oncology evidence-based management, oversight, or web authorization portals are likely to be a growing topic for discussion initiated by health plans and external vendors.

Risk sharing or shared savings models will arise from both health plans and providers, but may be a challenge due to comfort of one party or the other, or may be self limiting if based predominantly on early, easy solutions. Different geographic markets, with different health plan and provider mixes of academic, private and hospital-based cancer centers are likely to approach oncology management in different ways – which may prove a challenge to larger national or regional-based health plans or providers.

Health plans are also likely to evaluate where their oncology policy and management initiatives will be based, in the medical benefit or the pharmacy benefit, or some combination thereof. Considerations will include whether current policy addresses drug management or full medical decision-making management, and whether both internal and external resources will be able to create programs over time that will integrate with the goals and direction of both the cancer providers and the health plan in the geographic market. The volume and costs of cancer care will continue to expand as a percentage of the market, so placement of medical or pharmacy benefit decisions will also be affected by state health exchange activities, employer migration in and out of the health benefit market, provider integration initiatives, and health plan innovation.

7. Trust – MD to MD, Will (and Must) Evolve for Success

As physicians and plans seek options to work together and find a common ground, three critical aspects are essential: 1) building trust), 2) hard data and 3) mutually accepted tools and rules for moving forward. Building trust involves understanding and listening to each other's perspectives. Actual data that both can review and understand to identify solutions will allow for a productive conversation. For example, physicians may be certain that they are managing hospitalization rates of cancer patients effectively, but a health plan may believe there is significant room for improvement. Only by pulling actual hospitalization rates, and integrating that data with specific patient clinical data from physician medical records, can both parties sit together and come to a mutual understanding of the true variation and opportunities for improvement. Neither party is likely to see the full picture in isolation.

Identifying Potential Oncology Programs – Not an Easy Task

Health plans are used to limited, but tangible oncology focused programs – drug reimbursement pricing, prior authorization processes, tiered drug formularies, and requirements for specific diagnostics and step therapy, but oncology management of programs of the future will be more focused on complex data sharing and evidence-based medical decision-making. Medical directors in the private sector may have difficulty keeping up with changes and new initiatives in oncology moving toward guidelines, pathways, more integrated oncology management and evidence-based care proposals. Many programs have been started over the last four to five years, and several of those closed quietly some time later. There are some pilots in process in different parts of the country: pilots around guidelines, oncology management, specialty pharmacy, and bundling of payments, among others. Despite frequent discussion regarding oncology guidelines and pathways, questions still exist regarding use of national standards versus other guidelines, definition of evidence, use of drug formularies, and depth of management. It is apparent that each project/pilot is unique to the plans and physicians and market involved, and that there will need to be significantly greater exploration of alternatives before a national solution is identified, if ever. No single workable solution appears to have yet been universally accepted, so health plans and providers will find room for experimenting with solutions that fit unique markets.

Opportunities with Oncology Groups

Several large independent oncology practices, many

state associations, and national groups like McKesson US Oncology, Community Oncology Alliance members and NCCN Centers have demonstrated great interest and innovation in proposing (and implementing) various oncology programs and pilots with key health plans in various settings. Initiatives with these organizations can provide useful stepping-stones to improving relationships.

Choices with External Parties

A number of external parties (P4 Healthcare, eviti, D3 Oncology Solutions, many pharmacy benefit managers (PBMs), many specialty pharmacies, CareCore Oncology, New Century Health, to name a few) are entering the oncology space – usually targeting services to plans for oncology or drug management. Health plans need to review potential programs carefully to look at fit with the geographic market and providers affected, and the potential impact of introducing an external vendor. Sometimes external entities can provide a strong benefit for all involved, other times they may become a source of dissonance.

Medical Benefit, Pharmacy Benefit or Oncology Benefit?

Some payers are reviewing their benefit structure and considering whether to shift oncology drugs between medical or pharmacy benefit, or to create a new category of oncology benefit. There are many differences, as well as much overlap between management of cancer drugs in the existing medical and pharmacy benefit structures. Patients are also widely affected by drug placement in one benefit over the other, making these analyses not simple at all.

Many specialty pharmacy organizations are building complex infrastructures and technology to provide services to health plans for managing oncology under either the medical or pharmacy benefit, or both.[5] When billed under the medical benefit, oncology drugs become part of the cost of medical services. J-Code billings link to the diagnosis, but offer limited information about the specific source of the drug used. If data analytics and reporting within the medical practice can track and document drug use in accordance with guidelines and evidence,there is less need for a health plan to engage in possibly redundant oversight. Drugs traditionally billed through specialty pharmacies are tracked by specific manufacturer NDC codes for each vial, and may offer rebate opportunities. However, with enhanced oncology provider software, as well as the imminent mandated national conversion to the ICD-10 coding system, software fields will soon be in place to track and bill drugs within the medical benefit at the NDC level between health plans and physicians. Physicians and hospitals, as a purchasing class of trade, receive lowest commercially available pricing from manufacturers, presenting a challenge for specialty pharmacies (that cannot purchase at those rates from manufacturers) to generate savings for health plans on drug costs in markets where ASP plus pricing (usually plus 10 percent to 12 percent or more) dominates.

Many of the drug oversight and management systems created by specialty pharmacies for management of drugs also are believed by providers to exist in the practices and cancer centers, and are increasingly being formalized and built into key elements of EMRs. With individual states increasingly considering or passing some version of "parity legislation"[6] that mandates parity in member obligation regardless of whether drugs are provided under the medical or pharmaceutical benefit, and the imminent software changes, health plans may be less likely to look at significant shift of drugs from one benefit structure to the other and instead focus on other cost-saving alternatives.[7]

The complexity of cancer offers significant challenges to pharmacy benefit models that require delivery of drug to the physician's office from a prescription or that relay on extended week or month prescription fills to achieve economies of scale. Patient health status and reactions to cancer treatments can create wide variations in the ability of the patient to continue the treatment over time exactly as originally prescribed. Even "short fill" prescriptions of costly cancer drugs can result in hundreds of thousands (or more) of drug dollars being paid by health plans for individual drugs that couldn't actually be used for that patient – or for any other patient once prescribed, labeled and shipped.[8]

Guidelines and Pathways for Oncology

Physicians, both treating and medical directors, patients and employers, turn to Federal Drug Administration (FDA) approved drug indications, nationally published guidelines such as those produced by NCCN and ASCO, and compendia that link specific drugs to appropriate indications for specific diagnoses when evaluating choices for treatment and coverage. NCCN Guidelines™ reflect consensus opinions from over 40 standing committees of leading physicians, and are identified as to levels of evidence and consensus (http://www.nccn.org/professionals/physician_gls/f_guidelines.asp.)

They are available in static form for free via the NCCN web site.[9] The NCCN Guidelines reflect recommendations across the full continuum of care, including surgery, radiation oncology, medical oncology treatments, imaging, diagnostics, supportive care, palliative care and maintenance and follow-up.

Exhibit 3: NCCN Guidelines® & Clinical Resources

NCCN Categories of Evidence and Consensus

- Category 1: Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
- Category 2A: Based upon low-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
- Category 2B: Based upon low-level evidence, there is NCCN consensus that the intervention is appropriate.
- Category 3: Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

All recommendations are category 2A unless otherwise noted.

www.nccn.org/professionals/physician_gls/f_guidelines.asp

Clinical trials are always a primary option under the NCCN Guidelines if one is available. The NCCN Drugs & Biologics Compendium (NCCN Compendium®) links specific drugs and J-Codes to specific NDC codes. The NCCN Compendium® does not include other non-drug specific information found in the NCCN Guidelines. (Exhibit 4)

NCCN does receive funding from pharmaceutical companies for many of its activities, and some health plans have raised concerns about the impartiality of the NCCN Guidelines and NCCN Compendium. NCCN Guidelines do not consider the cost of treatment and do reflect a wide variety of recommendations, at differing levels of evidence and consensus. Despite the occasional questions, it is clear that NCCN Guidelines and the NCCN Compendium continue to be recognized as the gold standard both because of the rigor and transparency of their review process. The NCCN Compendium is one of the few drug compendia that meet stringent federal standards for transparency and are a federally approved compendium resource for Medicare coverage. The NCCN Guidelines serve evidence-based care because they present the options, evidence and consensus that allow the treating physician to then determine the most appropriate treatment for the patient's individual state and stage of disease and health status.

Until 2010, NCCN Guidelines were only available in static form, and EMR companies didn't have licenses to integrate the NCCN Guidelines into their decision-making algorithms. In 2010, NCCN partnered with a software technology company to create a Web-based portal that allowed physicians to enter patient specific stage and stage of disease. The physician would be presented with an information page showing the levels of evidence and consensus for each treatment indicated in the NCCN Guidelines, plus information on practice and health plan policy for treatments, and eventually, tracking utilization of different NCCN Guideline options by physicians treating similar patients. This software algorithm, called CDS Oncology, is now owned by McKesson Specialty Health (McKesson) and is being integrated into its service options for oncologists

Exhibit 4: NCCN Guidelines® & Clinical Resources

About the NCCN Drugs & Biologics Compendium (NCCN Compendium™)

The NCCN Drugs & Biologics Compendium (NCCN Compendium™) lists appropriate uses of agents defines in and derived from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines™). As such, the uses listed in the NCCN Compendium are based upon the evaluation of evidence from scientific literature, integrated with expert judgement in a consensus-driven process. The NCCN Compendium is indexed by drug or biological agent whereas the NCCN Guidelines are indexed by disease. The NCCN Compendium identifies the pharmacologic characteristics of each drug or biological and includes information on route of administration, as well as the recommended uses in specific diseases. The indicated uses are categorized in a systematic approach that describes the type of evidence available for and the degree of consensus underlying each recommendation. All recommendations (at all category levels) in the NCCN Compendium constitute appropriate, medically-necessary care.

Clinical professionals should apply independent medical judgement in their decisions about treatment that meets the clinical characteristics and needs of individual patients with cancer. Also note that the NCCN Compendium's listings represent the conclusions of the NCCN Guideline Panels as of the date of finalization of the relevant NCCN Guideline. NCCN Guidelines are updated continuously.

The NCCN Compendium™ is updated in conjunction with the NCCN Guidelines™ on a continual basis. The latest NCCN Guidelines and Compendium updates can be accessed at NCCN.org

www.nccn.org/professionals/drug_compendium/content/about.asp

and health plans. McKesson and NCCN announced in late 2012 a new partnership to develop "Value Pathways Powered by NCCN" that will create software to assess treatment options consistent with evidence-based standards, as well as to consult coverage policies mandated by payers. The software will be available on the market in the spring of 2013. This collaboration is hoped to drive a single set of standards in the market place, which would be based on NCCN Guidelines.[10]

Two clinical entities, US Oncology and the University of Pittsburgh Medical Center, created similar formal processes of review among both academic and practicing physicians, and developed their own preferred oncology pathways – Innovent Level 1 Pathways[11] and Via Oncology Pathways (now known as D3 Oncology Solutions)[12], respectively. Both models have been offered to health plans and practices, with some, but not universal, success. Both of these entities have identified tangible cost savings and quality of care enhancement through utilization of their pathways. Each built care preferences by first reviewing potential equal clinical effectiveness, comparable toxicity and side effect profiles, and lastly, if possible, comparable costs of care.

Other non-commercial entities, P4 Healthcare[13], eviti®[14], New Century Health[15], and various specialty pharmacies ventured into creation of either oncology guidelines or pathways, but have also met with mixed success. Individual pilots and programs have been started in specific geographic areas, but none has achieved universal acceptance and uptake from all oncology providers in any of these markets. New Century Health is licensed to integrate the NCCN Compendium into its technology. The NCCN Compendium links specific drugs to appropriate diagnosis codes according to the NCCN Guidelines, but does not integrate surgery, all diagnostics, imaging, radiation oncology and palliative and supportive care as the NCCN Guidelines do.

This wide variation in "guidelines solutions" poses a challenge for health plans and physicians in oncology. National guidelines such as those produced by NCCN enjoy broad acceptance among most oncologists, but have historically had limited electronic options for tracking and monitoring them. Clinically driven pathways may be a viable option, but are too big a leap for practices/physicians that remain comfortable with the national consensus guidelines. Commercial programs may enjoy acceptance among the small group of physicians who may have been tapped to vet their own versions of guidelines or pathways, but usually fail to convince other groups to accept those versions in sufficient numbers to satisfy health plans seeking more universal solutions.

End of Life and Palliative Care Management

Most health plans and physicians would agree that the integration of palliative care discussions into care management for oncology is essential. The timing and format of such discussions is sometimes a source of difference of opinion. Usually the timing of the discussion is dependent upon the state of disease, and the progression of therapy, which is information held in the medical record with the treating physician. Professional oncology organizations such as ASCO and NCCN are addressing consistent process and content for such discussions among both patients and physicians. ASCO has published a Provisional Statement of Clinical Opinion: The Integration of Palliative Care into Standard Oncology Care.[16] Integration of palliative care discussions offers a good opportunity for collaboration between plans and providers for more consistent patient care.

Management Models in Oncology for Health Plans

There are a number of management models health plans have considered or used for oncology outside of their traditional contracting and claims administration processes with physicians and hospitals. The market has changed so rapidly that it is now easier to group them into categories. These models represent tools for managing cost, process or medical decisions in oncology. Many of the named vendors include components of the different models in their branded programs, and may not be limited to any one of these described tools.

Early Models -

- Drug management (CareCore Oncology, IC RE, many specialty pharmacies, P4 Health care)
- Disease management (Quality Oncology (Alere))
- Oncology management (ICORE)
- Radiation oncology benefit management (CareCore National)
- Back end (claims based) compliance tracking programs (P4 Healthcare)

Current Models –

- Specialty pharmacy/pharmaceutical benefit management and drug delivery (CVS Caremark Specialty Solutions, Walgreens Specialty Pharmacy, Express Scripts)
- External Guidelines/Pathways to Treatment (significant challenges) (eviti)
- Programs Based on the NCCN Guidelines/

NCCN Compendium (McKesson U.S. Oncology, New Century Health)
- Physician-Based Front End (tracked at the point of the medical decision) compliance programs (Innovent Oncology, D3 Oncology Solutions)

Emerging Models - MD/Payer Collaborations

The "Early" category presents the initial tools, now understood to have had a limited impact on the total cancer spend, and which appear to be giving way to other transitional models. These were mostly in play about four to five years ago:

- Drug management
  - Focused mostly on preferred pricing and for mularies for drug
- Disease management
  - Focused on the symptoms and side effects of cancer treatment
  - Usually involving banks of nurses with out reach to patients through vendors outside of relationship between the physician and the patient – and which has sometimes had a very difficult time proving return on investment (ROI).
  - Disease management companies have a challenge because they cannot accomplish what they want to without significant input from the practice and collaboration with the physician and the patient, which leads to the ROI difficulty.
- Oncology management
  - The concept of a vendor managing the oncol ogy issues for a health plan.
  - The primary example was a very visible pilot in Florida between a large plan and ICORE, which was announced prominently in the press, but slowed dramatically in execution, and industry watchers speculate that this is a model that may not survive the initial contract.
- Radiation oncology benefit management
  - This focuses on the oncology treatments, but recent challenges in states like NY have limited the scope and reach of these programs.
  - Claims-Based Preferred Treatment Compliance
  - P4 Healthcare has a claims- based preferred treatment compliance program that experienced early successes, but now is being eclipsed by newer programs with different technology and higher rates of acceptance by both physicians and health plans.
  - The early compliance program was based upon older technology that focuses on the "back end" (claims billed) of the treatment process rather than the "front end" of medical decision-making.

The "Current" category of programs includes many programs in various stages of implementation today. Many of these programs are in place, and generating information from their experiences. This has led to an understanding that there may be multiple steps to the process of oncology management, as opposed to single solutions with limited scope.

The market is now moving into a transitional phase. The current approach for most health plans and providers is to explore programs and to ask – how will this affect the full course of the disease, or the total spend – not just concentrate on a small component such as price of drug. Some of the pharmacy and disease management programs have experienced challenges and questions in terms of continuing return on investment.

Specialty Pharmacy

Oncology drugs are specialty pharmacy drugs. They are expensive, used by a relatively small percent of patients, require close medical oversight, demand detailed patient education and support, and are not routinely stocked in the local pharmacy. As outpatient oncology care evolved from the early 1990s onward, physician cancer practices would acquire the drugs from specialized oncology distributors and bill for the drug once it was administered. This became known as "buy and bill." Specialty pharmacies evolved over the same time period, but didn't actively enter the oncology market until the federal government proposed in 2002 a Competitive Acquisition Program (CAP) as an alternative to "buy and bill." The CAP program was not a success, because just one specialty pharmacy signed up and less than 200 oncologists across the country elected to participate. While still a part of national law, the CAP program has in reality been retired by the Medicare program.

Whether specialty pharmacies should contract with health plans to universally replace "buy and bill" options with delivered drug to the physician practices is a frequent topic of conversations between specialty pharmacies, providers and health plans. Many specialty pharmacy programs are being developed out of a perceived need for more broad plan oversight and reporting, and as a natural evolution of the specialty pharmacy model into high touch, high cost, low volume drugs such as those used in oncology.[17] Most physician practices and hospitals have risk and liability reasons for preferring to use their own known drug sources, and few payer programs have successfully mandated on a wholesale level conversion to delivered drugs (also known as "script for ship") from "buy and bill". At least one

major specialty pharmacy, CVS, has indicated their own belief that the "buy and bill" model is the most efficient way to obtain and bill drugs for cancer care.[18] The CVS Caremark oncology management program is focused more on process, evidence-based care and information management than on delivery of drugs into the provider office. One challenge for many specialty pharmacy programs is that they may be developed for patients receiving care in physician offices, but not as ready to manage care delivered in hospital-based centers.

Specialty pharmacies offer services beyond drug delivery to payers. They also are now performing reporting and care analytics, patient drug interaction management, patient compliance and adherence programs, and oncology management services. In many states, physicians are prohibited from dispensing oral drugs (although hospital pharmacies are able to) and specialty pharmacies serve the oral markets in those states.

Oncology patients are complex. Their health status can vary widely. As often as 20 percent[19] of the time, patient health issues can result in a dose change or delay from the original intended physician order. Under "buy and bill," this is not an issue. Physicians order drugs in advance for anticipated treatments, but keep them in a centralized inventory until pulled the day of treatment once current health status is known and the treatment can be adjusted, administered, and then billed to the health plan. Under a delivered drug model, the drug is ordered by the physician in advance and arrives usually the day before treatment. If and when the patient presents with a health status that necessitates a dose or vial change that cannot be accommodated by the delivered drugs, not only does the physician have to come up with the needed drugs for treatment, but also the drug that had been delivered under a specific patient name has to be discarded per state pharmacy regulations. It cannot be repurposed for another patient or returned. A recent national study[20] to identify the potential impact on total drug costs for health plans if all cancer care were delivered under a delivered drug model rather than a "buy and bill" model demonstrated that one in 10 oncology treatments, on average, result in a significant variation from the original order, and could have led to over $1.1 million of drugs having to be discarded unused for the 1,368 patients in the study if the drugs had been delivered to the provider rather than provided under "buy and bill". About 90 percent of those variations resulted in the planned drug not able to be given to the patient at all. Earlier studies have indicated that additional costs of several thousand dollars per physician might be incurred.

Further information and review of pilot programs will be necessary to clarify the appropriate role for specialty pharmacies in the delivery and management of oncology drugs. Currently, most use of specialty pharmacies in oncology is for selected Medicare Advantage programs, some Medicaid programs, and selected use for individual drugs or smaller health plans by cancer providers, usually linked to their ability to cover drug costs under other models.

Guidelines and Pathways Contracting Experience

There has been extensive discussion in both payer and provider organizations (individually and sometime collaboratively) about guidelines and pathways programs, but there are only a few that have moved to executed contracts, and even fewer that have evolved into working programs. A number of contracted programs (in states such as Tennessee, Indiana, Georgia, Florida, Pennsylvania and others) appeared to hit snags in the implementation process and did not materialize as planned.

The few working guidelines programs (as opposed to announced programs that didn't materialize or that haven't received enough activity to be reviewed) rely heavily on physician involvement. They are in states such as Michigan, Pennsylvania, and Texas. Innovent Oncology, an affiliate of McKesson U.S. Oncology, has been the most active, with other programs of interest including D3 Oncology Solutions. The P4 model relies heavily on tracked compliance from the physicians billing system and it enjoyed early program development in states such as Michigan and Pennsylvania, but now has to compete with newer programs and technology.

Front end medical decision-making models (like Innovent, D3 Oncology Solutions and eviti) tend to engage the physician and track decisions made before treatment begins. The older, back end compliance models tend to use claims data following treatment to track compliance with predetermined lists of preferred treatments (like P4 Healthcare).

As of January 2012, there are now a limited number of companies that hold licenses to integrate NCCN tools into their decision-making algorithms in a non-static manner, including McKesson Specialty, which owns software that has been licensed for the NCCN Guidelines, and New Century Health, which has a license for the NCCN Compendium.[21] United Healthcare has also received a license by NCCN to integrate the NCCN Compendium in their claims processing and editing programs, so that practices submitting claims that are in concordance with the NCCN Compendium indica-

tions will be approved automatically. One condition of licensure from NCCN for external vendors is that all treatment options shown in the NCCN Guidelines must be made available to treating physicians. That requirement could pose challenges for vendors who seek to customize clinical pathways and narrow treatment options for health plan clients.

Physician/Plan Collaboration, including Oncology Medical Homes

As a result of direct past experience with the limitations of early adoption of specific tools (many of which affect, but do not include treating physicians), the growth focus in oncology programs now seems to be physician/payer collaborations. As these new collaborative programs emerge, they tend to be more long term, focusing on both current and future initiatives.

One national payer, UnitedHealthcare, has been working with five leading oncology practices to pilot evidence-based episode pricing options. The project has proved to be more complex than originally planned, and is still in process.

The increasing national attention to concepts such as Accountable Care Organizations (ACOs) and Patient Centered Medical Homes (PCMH) has focused mostly on primary care specialties, rather than oncology. There is one health plan, hospital and cancer practice partnership that has developed an oncology accountable care partnership, which started in 2012[22,23]. Practices in California, Michigan, New Mexico, and Pennsylvania have built their own models of an oncology patient centered medical home and are engaged in exploratory contractual relationships with key health plans in their areas, as well as with other practices across the country, to pilot whether the medical home concept can be adapted for oncology, and what that would look like.

Investigating Vendors and Programs in Oncology Management

Due to the sensitive nature of the disease itself, and the complexity of information involved in the decision-making, vetting external vendors or oncology management programs can be challenging. Some key questions to explore would include:

1. **Agenda** – What is their focus and agenda? What is their history in the marketplace? Are there any "advantages" or "baggage" that they bring to the table from past relationships for a payer, a physician or a patient?
2. **Actual History versus "Press Releases"** – There have been many cancer focused initia tives (and contracts) that have been announced in the public media in the last three to five years. Many of those faltered significantly within months of the press release, and have been dropped or allowed to fade away quietly. This is particularly true with vendors that tout contracts with payers or employers regarding oncology but then fail in execution because they cannot gain support or buy-in from the physician community. It is important to look behind the marketing material and to explore the current history with local providers.
3. **Track record** - It is also important to carefully review programs beyond the first six months. There have recently been occurrences where vendors have executed contracts with health plans, promising penetration and uptake within the physician community, and were unable to deliver on those promises. The usual cause ends up being trust (or lack thereof) in the vendor and/or in the program itself. The transparency and validity of the particular guideline or pathway source and development process is also important. Success is more likely with the usual clinician's perspective and trust of information and resources provided by NCCN or ASCO. In some circumstances, a vendor has started discussions with the physician community, been refused, and then gone directly to a health plan. The health plan received an unpleasant surprise after the program was announced and a majority of the key clinical physicians declined to participate.
4. **Return on Investment** – Most programs that focus solely on savings, particularly around drugs, tend to miss the bigger cost elements of the full continuum of oncology treatment. Disease management programs that focus on reduced hospitalizations and ER utilization but which do not actively involve full engagement and support of the oncology physician tend to offer self-limiting solutions, with diminishing rates of return.
   The further removed the physician is from the proposed solution, the less likely it is that the program will be able to offer return on investment beyond the low-hanging fruit, and the more likely it is that the program may alienate the very physicians that are most involved in the treatment of cancer patients.
5. **Focus** - Does the proposed solution address one component of the total cancer spend and go no further? Does it address, collect, and provide useful information to expand the understanding and management of cancer care,

both to those who pay for the care and to those who provide the care? Will it be a stepping-stone to more productive understanding of cancer or a dead end with little future gain? Does the proposed program constitute just one tool in a large and continual toolbox? Will it have the intended consequences when applied? Can it be adopted for use by both private and hospital-based care? Are there reasons why one of those models might find it challenging? Is that critical for you given the market dynamics of your own local area? What is your mix of private and hospital-based care?

6. **"Evidence"** - There are vast differences between use of evidence (and transparency in the definition of that evidence) to select treatment choices for coverage and the use of other criteria for treatment choice selection. Both physicians and payer medical directors will look closely at programs professing to be evidence-based. Key questions will include:
   a. What is the evidence source? Resources such as the National Comprehensive Cancer Network (NCCN) and American Society of Clinical Oncologists (ASCO) are considered the national gold standard for evidence-based care guidelines in oncology by physicians and health plans alike. To the extent that changes are made that vary from ASCO or NCCN Guidelines or NCCN Compendium, it will be important to clarify how and why such changes were made, and to prove to health plans, physicians and patients the justification for variation from the national standards. This is a particular challenge for programs that rely on small groups of physicians to edit and review an individualized program. While those physicians might agree to participate, that is not a guarantee that others will find the individualized program attractive, or that the changes made by the individualized program will not be challenged by some external entity.
   b. What is the connection to the evidence source? Some companies are licensed to receive updates and revisions directly and promptly from the nationally trusted sources, while others rely on publicly disseminated information about such changes – which adds to the potential for gaps in current knowledge in a rapidly changing specialty field. It is one thing to ask physicians to make life-altering treatment choices based on a program that is closely affiliated with and privy to direct licensed updates from trusted sources such as NCCN and ASCO. It is quite another to expect clinicians treating cancer patients to trust an external party to accurately collect, analyze and possibly modify the recommendations and treatment choices, especially if that party has no direct connection to NCCN or ASCO and relies on remotely published materials and information.
   c. Selective updating/information communication – Some companies take the nationally recognized gold standards produced by large standing committees of both academic and community physicians for cancer care, and selectively truncate or abbreviate the care recommendations for specific cancers. These choices usually operate outside of the traditional clinical evidence supported by practicing physicians, and, not surprisingly, often face challenges by physicians for limiting care options for individuals. They may also be challenged by health plans or patients, depending upon the source.
   d. Transparency – The national bar for transparency and rigor of recommendations for oncology treatments has been set by the Center for Medicare and Medicaid Services (CMS). There are several elements to the decision-making process for a compendium (which reviews available literature and studies in order to publish appropriate accepted treatments for use in specific cancers). One would expect that any guideline or pathway program proposed to health plans and physicians would follow the same degree of rigor and transparency in their own decision-making process.
      i. Track changes for not less than five years
      ii. List all evidence considered
      iii. List all participating individuals in review (credentials, disclosures)
      iv. Minutes and voting records kept
      v. Clean decision-making, with no agenda other than care

Unfortunately, many programs offering guidelines and/or pathways in oncology do not make such standards and processes routine or available for scrutiny and, thus, may raise concern.

7. **Flexibility** – Cancer treatment needs to be individualized. Patients even with the same

cancer diagnosis and stage will likely respond differently to the same medications, require differing dosage regimens, and will have different progression rates This is why physicians need the flexibility to adjust treatment choices when determining what is the most appropriate for each individual. Registries of real-time treatment that incorporate clinical information from the practice and non-practice cancer costs from plan databases will be the most effective way to build better understanding of the variations in clinical treatment effectiveness.

8. **Analytics and Reporting** - To better manage and understand oncology care, better data and reporting is needed, especially to the practicing physicians. Claims data by itself provides insufficient information to distinguish details such as stage of disease and patient performance status. The clinical data that is most essential to understanding and monitoring oncology care is found only in the physician's office. It requires many additional steps and much communication to translate clinical data into appropriate analytics and reporting so that it can become a continual feedback loop for enhanced clinical data management. The physician (whether private or hospital-based) is an integral part of understanding and evaluating this data. This puts the burden on external care evaluation and management programs to not only include the physician in an interactive manner, but also to return useful clinical information and analytics back into the hands of the physician for ongoing quality program development and enhancement. A key question for proposed oncology management solutions will be to identify what information is both obtained and provided back to the treating physician, and to assess its utility and ease of use.
9. **Operational Process** - What is the extent of burden of the management into the actual care process between the patient and the physician? Does it add costs to the system (for any of the patients, health plans or physicians)? What are the implications of those additional costs for access to care? Does it add overhead or distractions that may cause confusion? Does it add or reduce quality, timing and outcomes of the cancer treatment?

Moving Toward Real Oncology Reform

What is Real Reform in Oncology?

Given the rising cost of drugs, the complexity of care choices, the real gaps in information and technology to analyze and monitor real-time care progress, how do we achieve real reform in oncology to better be assured that the dollars being spent are being used as efficiently and effectively as possible? How can health plans and physicians and payers evaluate potential changes in benefit design and coverage policy related to cancer care, in addition to enhancing quality programs?

These are key elements to real reform in oncology policy and management:

1. Looking at the total cost of treatment, not just at the oncology drugs: Treatment choices are about far more than just drugs; they lead to costs and information, as well as individual patient health status and performance related to imaging, diagnostics, hospitalization, supportive services, palliative care, hospice, and increasingly, maintenance chronic management of the cancer. A new perspective focusing on the total cost of treatment will, of necessity, involve new software and analytics approaches, as well as changes in reimbursement and coverage policy, and even benefit design. The definition of "quality" becomes broadened, and more useful.
2. Focus on the basics of medical decision-making: This involves support and continuous feedback. Health plans and physicians both have different perspectives, but one common goal – to bring the right care to the right patient in the right setting at the right price. Cancer care is complex. Physicians hold the majority of critical clinical information, but could benefit from support in analytics and reporting, and feedback that includes information not usually available to them. Successful focus on the basics requires data sharing between health plans and physicians, which in turn demands a new process of collaboration. Trust is essential, but comes from agreement on the basics.
3. Start with trusted guidelines and track to real-time choices: The most basic elements of mutual agreement between health plans and physicians are the mutually recognized and trusted NCCN Guidelines and NCCN Compendium, and the ASCO Guidelines for Treatment. Each turns to these sources as the foundation for their own decisions and policy and would not make decisions without first looking at what the sources list as options. However, there is lack of agreement as to the degree of variation in current care measured

against these trusted sources. When health plans and physicians agree to monitor and review concordance against mutually recognized and trusted guidelines, the conflicts from perspective and opinion are able to fade into the background. Then a more productive discussion can begin about what variation is seen, what are the reasons for it, what can be learned from the information, what are the next steps and what issues should the team address?

4. Build Trust: Health plans and physicians are inextricably linked through the patient, but have had difficulty trusting each other or finding common ground for collaboration. A large part of that distrust is grounded in the lack of data as to whether care being delivered to these complex cancer patients is concordant with current evidence and practice for each patient given their stage of disease and health status. All other discussions about cost, choice of diagnostics, imaging, hospital and hospice resources, palliative care, and most importantly, drugs, stem from that initial question of appropriate evidence-based care.
5. Incorporate Strong Oncology Benefit Design with Effective Oncology Policy: Coordination of cancer policy in plans with employer benefit design and with effective medical decision-making by the clinician will achieve the best opportunity for quality and effectiveness in cancer treatment and care. NCCN has worked closely with the National Business Group on Health to build employer focused toolkits for evidence-based treatment recommendations for large employers. (http://www.nccn.org/about/news/ebulletin/2011-05-31/nbgh_update.asp). This initiative has led to the development of two tools to help employers with benefit design that will support quality and informed decision-making in benefit design for oncology care. The "Quick Reference Guide and Assessment Tool" provides a checklist of important cancer-related benefits, while "An Employer's Guide to Cancer Treatment and Prevention" provides a comprehensive set of tools to help benefits managers deal effectively with the challenges that affect both employees with cancer and their caregivers.

Barriers and Issues in Oncology Reform and Policy

Experience has shown the biggest challenges and threats to eventual success come from one or more of the following:

1. Missing the big picture: Either a health plan or a physician group may run the risk of limiting their attention to one aspect of cancer care, usually drugs, and failing to consider the ripple effects of decisions made solely related to that aspect.
2. Jumping forward too quickly and blindly: There are certain fundamentals that should constitute first steps in the process toward quality and oncology treatment and policy reform. (Examples of projects that may not be sustainable – 1) a physician group that decides to approach a plan with a home grown pathways program for contracting purposes, but without documentable proof or full transparency about how that program was developed, and without having the tools to understand within their own practice where there is variation and inconsistency in documentation and possibly treatment. Or 2) a health plan that has embraced a program that requires MD connection to a specific vendor, or which requires that the treating physician enter copious amounts of clinical information without understanding the overhead associated with manual reentry of clinical information kept in paper or electronic form in the practice, and without providing sufficient feedback and return information that is productive to the practice.)
3. Not knowing where the starting point is: Often teams sit down to negotiate complex contract and program terms without even having reviewed what the current care patterns are in the area and where the manageable issues may arise – or even looking together at the full costs of care variation. Vendors with tools and programs can contribute to the confusion by failing to understand the needs and issues of neither the health plan nor the physician community.
4. Not beginning with small steps, and very focused projects: If the initial projects are small, scalable and progressive at the beginning of a new relationship between health plans and either single practices or combined groups of practices, there is a much greater chance of success. There is an education process and a need to grow acceptance from the perspectives of both the physicians and the health plans internally in their own organizations, and the stakes are too high to risk a failed project.

5. Lack of two-way information flow: Physicians hold key clinical information in their practice records that does not reach the health plan through the claims administration process, but they sometimes are limited by their own technology to looking at individual care, rather than population or disease trends in their practices. Most health plans are not set up to collect the complex clinical information needed that is unique to the oncology care process of the individual. Health plans do have access to information on the elements and costs of care for individual cancer patients that occur outside of the physicians' office. Physicians cannot accomplish effective oncology management for health plans without better understanding the full impact of medical decision-making. Vendor tools that collect data from physicians without returning sufficient information back to the physicians are limiting the process and will not achieve long-term success.
6. Site of service does matter and is changing rapidly: There is an increasing dissonance between policy decisions made at the Federal level and private health plan policy. The Federal policy appears to be more supportive of the hospital-employed physician model, as well as close organizational integration between physicians and larger healthcare systems. Private health plan policy appears to prefer that mergers and acquisitions among health care providers not escalate, often citing concerns that the costs for similar care are higher in the hospital-based setting than in the private physician practice. Health plans and physicians are starting to engage in active dialogue about the pressures that make the practices consider acquisition as an attractive alternative, and are looking to create changes that may make that less likely. NAMCP has supported two studies in 2012 exploring questions related to potential changes in oncology management and cost. One study by Avalere Health showed that the total cost of care was higher for care delivered in hospital-based settings rather than private cancer practice settings.[24] The other study evaluated the impact that different delivery and acquisition models may have on health plan drug spend, showing that costs of drug delivered to the physician office could be higher, and also lead to significant amounts of drug that was shipped but not used for the prescribed patient having to be discarded.[25]

What Looms in the Future for Plans and Physicians Regarding Oncology Policy

Not only do the clinical options and evidence change rapidly for the treatment of oncology, but the public and private markets around those who deliver cancer care are rapidly shifting. Each one of these topics could become a game changer that dramatically redefines cancer care as we know it today. Health plan medical directors can, at best, remain aware of these trends, define their own policy to

Exhibit 5

Payer Spend Per claim per 1 Million Lives by Site of Service[32]

Ranking	J code	Brand Name	$ Per Claim - Hospital	$ Per Claim - Home Infusion	$ Per Claim - Medical Office
1	J1745	Remicade	$5,995	$3,255	$3,221
2	J9035	Avastin	$8,832	N/A	$3,024
3	J2505	Neulasta	$5,971	$3,410	$3,081
4	J9310	Rituxan	$9,068	N/A	$4,565
5	J9355	Herceptin	$4,877	N/A	$2,150
6	J9263	Eloxatin	$6,822	N/A	$3,677
7	J9170	Taxotere	$5,090	N/A	$2,287
8	J0881	Aranesp	$2,080	N/A	$1,077
9	J2469	Aloxi	$ 586	N/A	$ 303
10	J3487	Zometa	$4,169	$2,679	$1,607

adapt best for their own organizations, and prepare alternatives as these topics and trends evolve into daily practice changes.

Different Costs related to Site of Service

The oncology care delivery model has been shifting more rapidly in the last few years and private payers have started to seek and track information to determine whether this trend is shaped by policy and what effect these changes might have. An ICORE report on analysis of a proprietary data set (from 2009 and 2010 paid claims) from a number of regional and national health plans identified higher payments for specific drugs to the hospital setting than then private practice office[26] (see Exhibit 5). While current payment rates for any given health plan or provider may differ from those reflected in that study, the Avalere study referenced above also found that costs of care provided by hospital-based physicians can be higher than care provided by private practices.

Cancer Management policy that leads physicians to seek institutional sites of care for patients or to seek protection from lower or negative operating margins could inadvertently cost health plans significantly more for similar care. Hospitals are larger entities, with more significant overhead as well as greater negotiating presence.

Balancing the distribution of services in different sites will become even more important in future years as the oncology model shifts due to a shortage of oncologists. While it will be possible to triage certain treatments to "simpler delivery processes and providers" such as PAs and oncology certified pharmacists, the complexity of oncology care will still demand physician oversight and continued access to acute care facilities that can manage adverse patient events in a blink of an eye. Under the current reimbursement structure, it will also be difficult to push just complex care into some settings that now rely on a mix of complex and simple care in order to cover their overhead without simultaneously changing the reimbursement structure.

There may be opportunities for enhanced continuum of care coordination and quality initiatives in a larger integrated health institution under clinically integrated or shared risk models such as accountable care organizations. There may be economies of scale for patients. Providers of cancer care, no matter what the site of delivery, should be focused on achieving similar quality of care and continuity of care goals that will yield cost-effective care. Health plans and patients will benefit from care delivered in markets where the goals of quality are consistently met, regardless of site of service.

Drugs in the Medical or Pharmacy Benefit

Questions abound about what will be the role of specialty pharmacy and pharmacy benefit managers versus physicians in managing both the oral and injectable/infusible drugs involved in cancer treatment. Does the complexity of the cancer patient and the rapidly changing health status of patients lead to opportunities or barriers that affect the involvement of other entities besides the physician and the patient? Does current benefit design adversely affect patients in one setting or another? What is the impact of parity legislation in current and pending states on plan benefit design regarding oncology benefits? Parity legislation, often sponsored by the American Cancer Society, has been enacted or is under review in several states. This legislation, in its most basic form, is intended to mandate that the financial impact on a patient will not differ for cancer drugs whether or not the drugs are delivered under the medical benefit or the pharmacy benefit. The ICORE 2011 Oncology Trend Report[27] reports that as of February 20, 2011, 21 of the 50 United States were considering oral parity legislation, 14 had already enacted such legislation, and the other 15 had taken no action at that point.

Oral Drugs

Many health plans are concerned about the pipeline and imminent rise in the use of oral therapies in the management of cancer care. About 10 percent of the current oncology drug spend is from oral drugs. Oral drugs are not a panacea or replacement for many injectable/infusible therapies. Many oral drugs are used in combination with injectable/infusible treatments, and complications can arise for patients and physicians, as well as for plans if care delivery and timing are affected by benefit design or delivery issues related to types of treatments. Oral cancer drugs can be just as toxic as injectable agents, and require as much, if not more, oversight and management because the patient is not always in front of the clinician when taking the drug. Patients with oral drugs are making decisions about whether or not they are going to be compliant, or even fill the prescription, and some are even adjusting doses and compliance based upon drug costs or the impact of side effects – all of which can significantly affect the expected success or outcome of the planned treatment. One recent study by Avalere[28] found that one in 10 cancer patients doesn't even choose to fill their prescription. Oncology policy can have a large role in the ability of physicians to match the most appropriate therapy to the patient's situation, or in affecting whether or not planned treatment is executed in the most effective manner.

Individualized Medicine

Individualized or personalized, medicine is a growing area of interest for plans, physicians, employers and patients. The goal is to ultimately be able to determine at the outset of what the most effective treatment will be (if there is any) for a given patient with their state and stage of disease and medical history/profile. However, scientific discovery has not yet caught up with the market expectations for this aspect of care. Even where diagnostics yield results that would lead to an "indication of success or failure," there are still many grey areas that are subject to interpretation depending upon perspective. Even for a supposedly "clear cut" test like OncoType Dx™, where results in a certain range are interpreted as not indicative of likely response to chemotherapy, some patients continue to demand treatment under the hope that they will be in the very small percentage that will succeed. As a society, we have not yet come to the ultimate statement that treatment will be refused based solely on diagnostics. This is about the choice of the individual, and whether, when faced with a patient that will continue with treatment regardless of the test results, a physician should make a "responsible" choice and not incur the cost of the diagnostic test. Consequently, the question of the effectiveness of current predictors for individualized medicine is still very much an open issue for plans, physicians and patients. Questions for active discussion between physicians and plans will include: Is the evidence there for policy decisions? How much can we rely on the diagnostic tests now available and those coming in the pipeline? At what point does the level of trust tip toward the effectiveness of the test? There is definitely a good deal of potential and hope on the horizon, but currently this is still a very grey area for oncology management.

Emerging Treatment Options – Biosimilars

In the past 20 years recombinant biologics that target specific receptors and disease mediators have made a substantial impact on diseases including arthritis and cancer. These drugs are also considered a driver of escalating health care costs that continue to increase on an unsustainable trajectory.[33] The arrival of biosimilars in the United States (U.S.) represents a potential opportunity to constrain health care spending while increasing access to these important treatments for patients who can benefit from them. Concerns have been expressed in the U.S. market regarding biosimilars. Paramount is that cost savings may come at the expense of quality, safety, or efficacy. However, recent European experience with rigorously evaluated and approved biosimilars has demonstrated that savings, as well as improvement in access, can be achieved without compromising patient outcomes. Time will tell whether similar success can be achieved in the United States.

Biosimilar Development and Regulatory Process: General Principles

The scientific concepts supporting a determination of biosimilarity, or high similarity, are universal in tightly regulated markets such as the United States and Europe, and have been in use for many years to enable changes to be made in the manufacturing processes for originator biologics.[34] In order to establish biosimilarity, a sponsor must first show that the candidate product is highly similar to the originator (reference) product at the analytical level, including structural characteristics and biological functions. To do this, a sponsor must initially perform a detailed analysis of the originator product, using a variety of analytical techniques to measure multiple attributes in multiple ways.[34] Because all biologic products (including originators) vary over their lifetime, multiple batches of originator product must be acquired over time, and multiple analyses are performed over the shelf-life of each batch. Batch-to-batch variability in the reference product is often minimal, although larger variations can occur (for example, after manufacturing changes). Importantly, because both pre- and post-change products are concurrently marketed and administered to patients, the range of variation between the products, with respect to product attributes, is presumed by manufacturers to be acceptable to regulators[35] and judged as having no impact on the clinical effectiveness or safety of the product. This extent of the variation of the originator defines the boundaries, or "goalposts," of acceptable features for the biosimilar.

Biosimilar product development involves an iterative, target-directed approach until its product attributes are within the "goalposts" set by the originator. Any parameter for the biosimilar that is outside the expected variability of the reference product must be shown to have no impact on the clinical attributes of the final product. At this point a sponsor can conclude that their candidate is "highly similar" to its reference product. Developing a biosimilar requires a thorough understanding of the relationship between the manufacturing process and the resultant product, as well as the relationship between the molecular structure and its function.

Subsequently, the sponsor and the relevant regulatory body will agree upon the preclinical and clinical studies necessary to remove any residual uncertainty around the biosimilarity of the candidate. In highly regulated markets such as the United States and Europe, clinical data are currently a prerequi-

site for obtaining approval for biosimilars. Clinical trials will typically include clinical pharmacology studies to demonstrate bioequivalence, and efficacy and safety trials in a patient population confirming biosimilarity, either using equivalence or non-inferiority trial designs. The extent of the

clinical trial program required will be informed by the comparability of the proposed biosimilar to the originator. Highly similar product attributes would justify a tailored or abbreviated clinical trial program. Usually, the efficacy and safety trial is conducted in the most sensitive and relevant indication so that differences, if any, between the originator and the biosimilar can be elucidated. If no differences are observed and biosimilarity is confirmed, extrapolation to other indications that appear in the originator product label can be justified.[34]

What Benefits Can Biosimilars Bring to the United States?

The general expectation is that by introducing greater competition to the marketplace, biosimilars will have the potential to generate savings for the health care community, and also to provide expanded access to high-quality treatments for severe and life-threatening conditions. Several examples of how uptake of biosimilars can improve patient care are available from Europe, where the first biosimilar was approved in 2006. In a non-interventional study conducted in a community oncology center, switching patients from originator filgrastim to a biosimilar product resulted in more frequent use of filgrastim as primary prophylaxis,[36] which would likely reduce the number of patients developing febrile neutropenia. Another potential way in which biosimilars could lead to improved patient care is through greater access to life-extending or life-saving therapies.[37] In a very recent example, the budget impact of switching patients with cancer and chemotherapy-induced anemia to biosimilar epoetin alfa in the European Union G5 countries (Germany, France, Italy, Spain, the UK) was evaluated.[38] The authors also constructed estimates of the number of patients who could be provided with targeted anti-cancer therapy using the calculated cost savings. Based on 100 perent conversion of eligible patients to biosimilar epoetin alfa, cost savings of $140 to $186 million (depending on dosing strategy) were estimated, which translates into an additional 9,770 to 12,913 rituximab treatments, 3,912 to 5,171 bevacizumab treatments, or 3,713 to 4,908 trastuzumab treatments.[38] Furthermore, with over 500 oncology biologics currently in clinical development, greater use of biosimilars may release funds for these new cancer therapies.[37]

The Current Biosimilar Landscape

The biosimilar market in Europe is well established where biosimilar filgrastim is used more often than the originator. In oncology, the focus of biosimilar development is shifting from medicines used in a supportive care setting towards life-extending or life-saving treatments. Much like novel therapeutics, some of the challenges to uptake of biosimilars in the U.S. market include physician desire to "test" the actual performance of the drug in their own patient population before adopting any significant shifts. Payer concerns that savings may not be as significant as projections from the European market might suggest, payer reluctance to push physicians, especially oncology physicians, into a wholesale shift until the medical community expresses confidence in the U.S. market regarding biosimilars.

In the United States, the first biosimilar approval by the Food and Drug Administration (FDA) was anticipated by March 2015 if the FDA accepted the Biologics License Applications that were filed under the new biosimilar pathway. The FDA panel did approve a biosimilar for filgrastim in January 2015. Though it remains to be seen what the actual utilization and impact will be, the FDA's acceptance of filings by leading companies, such as Sandoz, Actavis, and Hospira, is an important first step in enhancing U.S. patient access to affordable, high-quality biologics.

Summary of Biosimilar Landscape

A regulatory framework is now in place in the United States to allow for the evaluation and approval of biosimilars. Regulatory science has been developed to monitor that these products have the same efficacy and safety as the originator biologic medicine on which they are based. In the face of ever-greater financial constraints on health care systems, biosimilars may offer an opportunity to provide high-quality and clinically effective medications at a reduced cost. If utilized as projected, biosimilars may enable greater adherence to recognized guidelines and could potentially subsidize novel therapeutic regimens which may also result in improved overall patient care.

The Role of Accountable Care Organizations (ACOs) and Medical Homes in Oncology

Most ACO initiatives, particularly those supported by the federal government, are focused on primary care and do not yet address oncology. There is a good deal of discussion and movement around the preparation of ACOs, but at the same time, many of the organizations initially identified as "ideal ACO candidates" for federal projects are so far declining

Exhibit 6

Essential transparency aspects of any proposed guideline or pathway tool for both plans and practices include:

- Direct licensed connection to NCCN and ASCO resources
- proven ease of use and acceptance for physicians in a busy practice setting
- Integration of the tool output into the practice clinical records system (manual or electronic)
- Detailed reporting available on at least a monthly basis to the physician on individual and all patients, trends, concordance with guidelines or pathways, for use in further clinical decision making (tools that merely report concordance or compliance with the program are insufficient). Examples of appropriate reporting include concordance and treatments by state and stage of disease.. retrospective and prospective cost summaries for patient care.
- Active engagement of the physician in the review of the program and full understanding of the components and transparency of the process
- Full transparency of the program for inclusions and more importantly, exclusions from drugs and treatments identified with any level of evidence in the NCCN Guidelines and/or Compendium
- Not limited solely to drug choices, but also should integrate diagnostics, supportive care, and be usable by both physician practices and hospital settings for the full continuum of care (very important given the increasing percentage of hospital-based care in many markets)

to participate under the terms of the federal models. Leavitt Partners announced a June 2012 update on the 221 ACOs it has been tracking in 45 states the following findings[29]:

1. The number and type of ACOs is expanding.
2. Growth is centered in larger population centers.
3. Hospitals systems continue to be the primary backers of ACOs, but physician groups are playing an increasingly larger role.
4. Non-Medicare ACOs are experimenting with more diverse models than Medicare- backed ACOs.
5. The success of any particular ACO model is still undetermined.

The patient centered Oncology Medical Home concept for treatment defines the oncologist as the hub for managing patient care and costs associated with cancer. One challenge for this model is the discussion of the role for managing co-morbid conditions or cancer patients that do not move into chemotherapy (surgical patients or those treated by dermatology or urology physicians). An opportunity for this model is the increased coordination and management of patients for services such as hospitalization and diagnostics while under active oncologic treatment.

There are at least four existing initiatives where practices have negotiated oncology medical homes pilots with local plans. The execution of an oncology medical home is a costly and complicated process for an oncology practice, and the implementation of an oncology medical home pilot between a plan and a practice will require a high level of trust and sophistication in oncology contracting on both sides. Medical home contracting is not likely to be the first model negotiated between a plan and a practice in any given market, but could be an escalation of prior, successful collaborative arrangements and pilots – usually process driven. Pilot oncology medical homes are now found in CA, FL, MI, NM, NY, MA, OH, PA and discussions between payers and providers regarding oncology medical homes are growing. The Community Oncology Alliance (COA) has a growing oncology medical home initiative with guidance from health plans, physicians, practice administrators, patients and patient advocates, among others.[30] COA has put together a list of informative resources on the Oncology Medical Home and ACOs (http://www.communityoncology.org/site/medical-home-aco.htm One challenge is finding interest and technological capability to address the complexity of the oncology medical home concept in both a health plan and a provider in a given market geography. Many examples exist where one or the other is interested and capable, but not both.

How do we define "Evidence"?

A key aspect of oncology management is the expectation that oncology care will follow accepted evidence-based treatments. However, the source of the definition of "evidence" should be mutually acceptable to plans, physicians and patients. Historically, the NCCN Guidelines, NCCN Compendium and ASCO Guidelines have been recognized as the primary resources available for oncology care. The process for creating these guidelines is

transparent and rigorous, involving both academic and practicing physicians (Exhibit 6). Treatments reviewed under the NCCN process are assigned varying levels of evidence and consensus and are updated quarterly to reflect the rapidly changing body of knowledge surrounding oncology drug discovery and treatment.

The NCCN Compendium is a different resource that includes discussion of drugs and treatments that have been identified in the NCCN Guidelines, but are indexed by the drug or biological agent. The NCCN Guidelines are indexed by disease. The NCCN Compendium addresses the pharmacologic characteristics of each treatment, and use in specific disease. It also includes information on route of administration.

Both ASCO and NCCN have developed extensive clinically driven resources for diagnostics, supportive care, clinical tools, decision aides, and patient guides specific to cancer drugs and disease. Most health plans utilize these tools as the basis for their own coverage policies.

Cost of treatment has not been addressed in the NCCN or ASCO reviews. Some physician groups, most notably U.S. Oncology and the University of Pittsburgh Medical Center, through their respective Innovent and D3 Oncology Solutions programs, have developed their own versions of clinical guidelines and pathways. In these versions, physicians reviewed the levels of evidence publicly available, and determined treatments which were prioritized in terms of similar efficacy and toxicity, and then, where possible, considered cost of treatment.

As practice technology evolved, and oncologists started to adopt electronic medical records, there was increased opportunity to select treatment choices and drugs from within the software. However, until April of 2011, there were no licensed solutions that allowed integration of NCCN Guidelines in a decision-making algorithm process (NCCN Guidelines were available only in static, reference form). Consequently, other programs were developed that were loosely based upon the static references. Individual practices, oncology management companies, and programs such as P4Healthcare and eviti developed their own versions of guidelines and pathways. However, uptake of these individualized programs has been sporadic, and not universal. This has presented challenges to health plans, who seek solutions that will be accepted by all physicians in their markets, not just the few who may have developed internal solutions, or proposals coming from vendors without physician support.

It is clear that clinical decision-making following a guideline or pathway process does reduce variation and lead to effective care and ultimate cost savings over care with more variation. However, clinicians first and foremost understand that cancer is an individual disease that can present and respond differently in each person. This is why clinicians prefer to work within the parameters of the evidence that is put forth by their trusted sources and tend to be very suspicious and reluctant to work with guidelines or pathways that have been developed by others, or represent limitations or abstractions of the NCCN or ASCO based clinical tools.

"Evidence" and the distinction between different sources of "evidence" are hot topics for discussion between plans and physicians. Successful programs will start from a mutually accepted definition of evidence. With the advent of tools that utilize these specific sources in an electronic decision-making algorithm, it will be far easier for plans and physicians to produce mutually acceptable data of concordance. It will be important for plans to carefully consider other tools, and to require direct licensing connections of those tools to the NCCN and ASCO sources, for credibility or more universal acceptance of alternative programs by the physicians in their markets.

One frequent health plan challenge to the clinically preferred NCCN and ASCO guidelines is that they include all possible treatments, and there is a desire to narrow that band width to the most appropriate treatments (including a review of cost of treatment). Physicians typically respond that they are following NCCN Guidelines and that they are treating individuals appropriately because of the individuality of cancers. It can be difficult to get off the "he said, she said" rollercoaster because details of clinical treatment essential to determining placement against guidelines are not included in the claims administration data.

Because the technology systems in oncology today (even oncology EMRs) have limited ability to track specific concordance to the exact NCCN and ASCO guidelines, which are the most commonly accepted standards for both health plans and physicians, such tracking has the chance to become the first collaborative project between plans and physicians. Until there is a mutually accepted depiction of real world treatment concordance and variation, it will be difficult to establish a baseline and common trust for further projects and discussions. Plan programs that move directly to higher control and limitation of treatment options, without reviews of whether real world variation exists to a great extent in their markets, may be vulnerable to physician challenges and resistance, in addition to possible patient challenges of restriction from standards of care.

Comparative Effectiveness in Oncology Management

Until we know what is currently being done in order to create a complete picture of the total cancer spend, it will be difficult to move into comparative effectiveness models. The crux of comparative effectiveness is that there is understanding of the full impact of treatment x versus treatment y, including costs incurred in the outpatient and inpatient settings. Building a full picture of the total cancer spend and patient impact for different treatments will lay the groundwork for true comparative effectiveness for oncology. The limited explorations into comparative effectiveness to date appear to have been focused solely on the cost of drugs in different regimens, which is a completely different question, and may miss a large piece of the picture on oncology decision-making and spend.

Impact of Federal Policy Changes

Despite what private health plans do in the next few years, there may be seismic changes that occur to oncology delivery and treatment that are driven by federal policy, and which may actually move counter to private health plan and employer preferences for such delivery models. Because Medicare patients constitute about 50 percent of all cancer patients, Medicare policy matters to oncology providers. Adverse Medicare policy changes will in turn affect the financial viability of the oncology physician and hospitals to provide care to Medicare patients, and in turn will affect not just health plans with Medicare Advantage programs, but also fully private programs. To the extent that Medicare reimbursements fall below costs to provide care, and push physicians into hospital employed models, private health plans may see their net costs of care rise solely due to the change in site of delivery.

Oncology Physician Shortages

There is a known pending shortage of oncology-trained physicians. This will drive delivery model changes, and site of care changes. Even with a potential increased base of physician extenders (such as PAs and oncology-trained pharmacists), it may make direct collaboration with the remaining oncologists to oversee and manage the total spend in oncology care more essential. It is far easier to use remote vendor and external management tools in a market that is crowded and over capacity. The oncology provider market is shrinking at a time when the expected incidence and need to manage cancer care is rising, so each remaining oncologist is likely to be more important to each health plan and employer.

National Association of Managed Care Physicians (NAMCP) Medical Director Member Interests and Initiatives

NAMCP member interests regarding oncology

NAMCP surveyed its medical director members about their oncology concerns and interests in 2010 and 2012. In 2010, when asked about utilization of NCCN Guidelines and the NCCN Compendium, 86 percent of the respondents stated that they used the NCCN Guidelines, and 77 percent said that they use the NCCN Compendium. When asked about use of external oncology benefit managers, the vast majority, 86 percent of the respondents, stated that they did not use such external vendors. When asked what were the five major issues related to cancer in their organizations, 100 percent of those who responded noted a concern with the costs of cancer, 67 percent of the respondents were looking for some definition of "appropriate" care, while almost half (42 percent) were concerned about end of life issues, management and costs. Other areas of concern included comparative effectiveness, imaging costs and management, site of service costs and variation, and quality.

NAMCP also asked its members in this survey about what they hoped NAMCP could provide as support for member management of oncology. Of the responses to this question, there was wide variation, but almost one-third (28 percent) of respondents sought information on comparative effectiveness, a quarter (25 percent) asked for information on advanced care planning and end of life management, and about 16 percent each asked for either assistance in treatment options, trends in oncology and staying informed, or information on oncology benefit management trends.

In 2012, NAMCP conducted two brief surveys of members related to oncology issues. In the spring, respondents noted that their top three concerns related to oncology were related to 1) clinical compliance with guidelines and evidence (35 percent), 2) the cost of oncology (28 percent), and 3) end of life management in oncology (8 percent). The vast majority relied upon NCCN Guidelines (80 percent) or NCCN Compendium (70 percent) for reference. Most medical director members (75 percent) chose not to use external vendors for oncology management. Of the 25 percent who noted they did use external vendors, 54 percent and 46 percent respectively used such vendors for Prior Authorization or Medical Review. Far fewer used vendors for treatment guidelines (38 percent), treatment pathways (25 percent) or drug pricing and disease management (25 percent each). Only 17 percent of the 25 percent who use external vendors did so for drug

delivery to physicians or patients.

These spring 2012 respondents showed 80 percent noting a variety of programs under development or in use with providers, including: prior authorizations (41 percent of the 80 percent with programs), use of NCCN Guidelines (34 percent), palliative care programs (27 percent), use of Web-based guidelines (25 percent), drug pricing/review (18 percent), use of preferred treatments (14 percent) and just 9 percent each were focusing on episodes of care or ER management in oncology. Medical management of oncology trailed far behind with 5 percent of the 80 percent who responded as participating in programs.

By the fall of 2012, NAMCP members responded to a survey of concerns related to oncology. The focus of concern appears to have migrated toward the concept of defining value in cancer care. More than 60 percent of the respondents noted their highest concerns were ensuring that drug treatment is balanced for clinical and cost effectiveness (75 percent ranked this concern as 4 or 5 - highest ratings for a scale of 1 to 5), ensuring treatment choices are appropriate for the disease (71 percent total ranked this 4 or 5) concerns about the rate of future oncology drug spend (75 percent total ranked this 4 or 5 – but mostly 4), and integrating palliative care management with active treatment (64 percent ranked this 4 or 5). The lowest concerns for this group of respondents were using external vendors for outsourcing oncology management (just 27 percent ranked this a 4 or 5 - the highest rankings on a scale of 1 to 5), and hospital acquisition of private oncology practices (only 17 percent gave this concern the highest 4 or 5 ranking).

While cost remains a constant concern for NAMCP medical directors of health plans, employers and integrated systems, the concern for defining and evaluating based upon value is rapidly rising. Value is increasing not just about the cost of the drug, but in also looking at the residual clinical effect (positive and negative) of the act of treatment, and in assuring that appropriate treatments are being selected. NAMCP members have also expressed an interest in identifying the landscape of the oncology market, in creating a framework for effective review of options and alternatives for managing oncology, and to facilitate discussions between plans and providers toward effective, collaborative oncology management.

NAMCP Oncology strategies and initiatives

Clearly, there are many rapidly changing elements involved in the management of oncology whether from the perspective of the plan, the purchaser or the physician. Under the guidance of Dr. Ron Hunt, President of NAMCP and of Blue Cross Blue Shield of Georgia, and Dr. Bill Williams, Executive Vice President, NAMCP is dedicated to improving communications between those diverse perspectives for the goal of improving patient outcomes. The Oncology Institute Executive Leadership Council, headed by Dr. Alan Adler, of Independence Blue Cross Blue Shield, has created a strategy and plan for addressing the interests and needs of the NAMCP members. They continue to move forward with these initiatives, and to solicit feedback from members and to support the industry at large in order to better improve patient outcomes in oncology. For medical directors, the value equation becomes a function of benefits over costs, and by moving forward with plans, purchaser and physician medical directors, the hope is to be able to improve benefits, enhance communications and collaborations, and to reduce costs of care overall.

Oncology Education - One first step was to survey the members for their key interests and concerns. As a follow-up to the members' request for more information on trends in oncology, sessions have been added to the programs presented at NAMCP conferences, a teleconference was added to present key oncology issues, and this NAMCP Medical Directors Guide: Oncology was developed to serve as a resource.

Oncology Resources - NAMCP presents a focused Oncology Track at each spring and fall national conference to discuss both clinical advances and trends in oncology management. An Oncology Web Based Resource Center has been created for the Oncology Institute, which will also include separate Medical Director Web Based Resource Centers as they are developed for specific cancers. The Multiple Myeloma Resource Center is now available on the website as are Resource Centers for Breast and Lung cancers. In addition, the NAMCP Oncology Institute website will provide tools and resources for medical directors, as well as patient resources and tools.

Interactive Discussion - NAMCP sponsors a discussion group for the members of the Oncology Institute for addressing specific or general oncology issues, questions, and concerns. Besides the breadth of organizations involved in the NAMCP as members, there are several Corporate Partners now engaged in discussions and providing resources related to oncology care through the Oncology Institute. NAMCP has also engaged an oncology consultant with deep experience in the issues and perspectives of plans, employers and physicians, as a resource to the organization and its members for oncology strategy.

Oncology Research Studies - NAMCP is also actively engaged in projects to identify and analyze research data on oncology issues, in order to facili-

tate informed policy decision-making and actions among its members.

NAMCP has entered into discussions for potential collaborations with key oncology provider organizations such as ASCO and NCCN. The Community Oncology Alliance (COA) and NAMCP conducted a study on the cost variations between site of service delivery models – of increasing importance given the trend toward hospital acquisition of private practices.[31] Another project with COA is exploring the concept of the oncology medical home, to see if there is potential for the concept that could bring value to the plans, physicians and patients, thus reducing costs by bringing greater efficiency to the process.

As discussed earlier, NAMCP completed a study that tracked the impact on drug costs of different drug delivery models.[32] Further evaluation of this issue is expected in 2013.

Other potential studies for NAMCP members will be to explore collaborative evidence-based oncology management and decision-making. These studies could be intended to see if this type of project could develop a mutually accepted model to explore existing variation (or not) from evidence-based treatments and serve as a rallying point for collaboration for further oncology- based initiatives in those markets. If successful, better tracking of evidence-based treatment could result in reduced overhead costs, for both plans and physicians, including lower costs for of oversight processes like prior authorizations, and better care for the patients and system at large. Those interested in any of these studies or in suggesting other initiatives may contact Katie Eads, in the NAMCP office (keads@namcp.org).

Next Steps and Action for Health Plans and Employers

Oncology is a complex disease, touching most Americans in their lifetime. Historically, it has been a brutally fatal disease, but is now evolving into a manageable, chronic disease. Every year, more is learned about ways to identify and define tumors, and to target them for more precise treatment. There are challenges that come with these successes: When more cancers are identified earlier, there is a better hope for successful treatment, but people may live longer – requiring more medical resources over the course of their lives to manage the disease. Clinical trials are always a viable treatment alternative for cancer patients, but by their nature, and the nature of Federal Drug Administration (FDA) expectations for clinical drug approvals, most new cancer drugs evolve into combination therapies, or may first be approved for more advanced cancers, and then build peer-reviewed evidence for other applications. The role of oncology compendium, tracking these new peer-reviewed applications, is an essential stopgap between the FDA initial drug approval and real-world experience. The NCCN Guidelines, while considered broad by many health plan medical directors, do reflect the varying levels of consensus and evidence that a rapidly changing field like oncology (where delays to treatment can become a matter of life or death), and provide a universal basis for evidence-based discussions between payers and providers. However, data collection and records technology is still severely lacking for both providers and payers, and will continue to evolve rapidly. The costs of oncology are now known to be far more complex than simple prices of individual drugs, and programs are developing between payers and providers to monitor, analyze and address these costs on a collaborative basis, even if such collaborations are unique and not yet fully scale-able to a broad market.

Medical directors of health plans, employers and integrated providers face new challenges in managing oncology. Resources such as this guide will help to lay the framework and context for action. Further explorations of individual topics, including palliative care, payer physician programs, ACOs and oncology medical homes, and defining/supporting evidence-based clinical decision-making will develop as other topics in the NAMCP Medical Directors Guide series.

Next Steps for medical directors will include:

- Comparing your local market pressures and evolution to the perspectives in the NAMCP Medical Directors Guide: Oncology.
  - What oncology management tools have been employed in your market to date and what have been the results? Successes? Limitations?
  - Who are the clinical leaders in oncology?
  - What delivery model changes have been happening?
  - Are there ACOs in development and has oncology been considered in that process?
  - Are there state associations or key clinical leaders in oncology who can be contacted, or who may have made their interest in working with you visible in the past?
  - Are external vendors seeking your attention related to oncology? Have you evaluated them under the suggestions set forth in the NAMCP Medical Directors Guide: Oncology? And are you ready to move forward with them; the clinicians in your market; or some combination?
  - Utilize the resources available through NAMCP for general information and

comparisons of opportunities/alternatives.

- Start the conversation
  - Reach out to the key oncology leaders (both private and hospital based in the market)
  – ideally to leaders where there is a known commonality of values and interest.
  - Identify differences in perspectives.
  - Clarify differences and potential commonalities of goals of all parties, and seek common data platform for initial discussions and evaluation.
  - Identify quality, value and financial impact of programs.
- Take the Next Step
  - Start the first pilot.
  - Set expectations realistically, and recognize the challenges and barriers that may arise.
  - Establish plan for resolving conflicts and continuing to move forward.

Conclusion:

Cancer is a very complex disease, and of great importance to plans, purchasers, physicians and patients. Many health plans have not yet adopted significant oncology management processes, but are increasingly concerned about how changes in the marketplace will affect them and the members they cover. These changes include site of service shifts, depth of the oncology pipeline, lack of detailed information about oncology treatments in relation to evidence, prices of drugs, and lack of predictability of costs for a disease that can both be fatal and chronic.

Oncology physicians are concerned about federal and private payment and coverage policy, the costs of drugs that they pay for in advance of reimbursement, the access issues their patients are facing through benefit design and oncology management processes, and how to prove the quality of their care in a challenging technology environment.

Purchasers (employers) are concerned about the impact of health costs and benefits on their own organization's financial viability, as well as the impact that cancer will have on their employee population.

Patients are concerned about whether their physician can afford to treat them in their preferred site of service, about whether they can afford the appropriate oncology treatment given drug prices and benefit design, and the daily mental and physical challenges of battling cancer. All these differing perspectives still ultimately have the admirable goal of wanting to see the right treatment, delivered to the right patient at the right time in the right setting, at the right cost.

There are a number of individual market challenges, driven as much by past relationships between plans and physicians as by other external challenges affecting oncology policy. There are many vendors shopping solutions to either plans or physicians, and careful evaluation of key elements of each program and vendor are necessary to avoid exacerbating an already volatile situation.

NAMCP as an organization is uniquely positioned to encourage mutual information sharing, discussion, collaboration, and analytics between its diverse membership of plans, purchasers and providers. NAMCP has also been able to initiate collaborative discussions with other key oncology organizations to bring a comprehensive set of perspectives to the discussion table. With the increasing activities of the NAMCP Oncology Institute, there are great opportunities for all involved to effect significant change and reform in the oncology space, while enhancing quality of care and patient outcomes even as they reduce overhead burdens and costs.

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Endnotes and Resources

1. "340B Drug Pricing Program and Pharmacy Affairs", a web page of the U.S. Department of Health and Human Services and the Health Resources and Services Administration (HRSA), Last Accessed on December 31, 2012, http://www.hrsa.gov/opa/index.html

2. "Treatment Update: Progress in the Treatment of Lung Cancer", Cancer*care* Connect Booklet Series, www.cancercare.org, Last Accessed December 28, 2012, http://media.cancercare.org/publications/original/18-ccc_lc_progress.pdf

3. "IBM Watson Finally Graduates Medical School", by Paul Cerrato, *InformationWeek*, published online October 23, 2012, Last Accessed December 31, 2012, www.informationweek.com/healthcare/clinical-systems/ibm-watson-finally-graduates-medical-sch/240009562

4. "CancerLinQ – building a Transformation in Cancer Care", a web page on the American Society of Clinical Oncology (ASCO) web site, Last Accessed December 31, 2012, www.asco.org/ASCOv2/Practice+%26+Guidelines/Quality+Care/CancerLinQ+-+Building+a+Transformation+in+Cancer+Care

5. "Specialty Pharmaceuticals: Manufacturers must consider a new supply chain", by Mark K. Barnes, *Specialty Pharmacy Times*, published online December 18, 2012, Last accessed December 28, 2012, http://specialty.pharmacytimes.com/publications/specialty-pharmacy-times/2012/December-2012/Specialty-Pharmaceuticals-Manufacturers-Must-Consider-a-New-Supply-Chain

6. "Oral/Infusion cancer drug parity begins to raise health plan costs", by John Carroll, *Managed Care*, January 2012, Last accessed December 28, 2012, http://www.managedcaremag.com/print/content/oralinfusion-cancer-drug-parity-begins-raise-health-plan-costs

7. "Some states mandate better coverage of oral cancer drugs", by Michelle Andrews, Kaiser Health News, May 14, 2012, Last Accessed December 28, 2012, http://www.kaiserhealthnews.org/features/insuring-your-health/2012/cancer-drugs-by-pill-instead-of-iv-michelle-andrews-051512.aspx

8. "Impact on health plan cancer drug costs in different delivery models", by Dawn Holcombe, Rex Force, Kerry Bradley, Joe Conoshenti, and Keith Huff, *Journal of Managed Care Medicine*, Vol. 15, Number 4, Pages 69 – 80. http://www.namcp.org/Journals/JMCM/Articles/15-4/PullDowns/Info%20CancerDrugCosts.htm

9. NCCN Clinical Practice Guidelines in Oncology®, National Comprehensive Cancer Network, Last Accessed December 28, 2012, http://www.nccn.org/professionals/physician_gls/f_guidelines.asp

10. "NCCN, McKesson form partnership to build clinical support software", *The Cancer Letter*, a publication of the National Comprehensive Cancer Network, November 30, 2012, Last accessed on December 28, 2012, http://www.cancerletter.com/articles/20121130_2

11. Home web page of Level 1 Pathways, the US Oncology Network, Last accessed December 28, 2012, http://www.usoncology.com/cancercareadvocates/AdvancingCancerCare/DeliverHigh-QualityCare/LevelIPathways

12. Home web page of D3 Oncology Pathways, a subsidiary of D3 Oncology Solutions, Last accessed December 28, 2012, http://www.d3onc.com/pathways/

13. Home web page of P4Healthcare, a subsidiary of Cardinal Health, Last accessed December 28, 2012, https://www.p4healthcare.com/

14. Home web page for eviti oncology solutions, Last accessed December 28, 2012, http://www.eviti.com/

15. Home web page for New Century Health, Last accessed December 28, 2012, http://www.newcenturyhealth.com/

16. "ASCO Provisional Clinical Opinion: The Integration of Palliative Care into Standard Oncology Care", web page on the American Society of Clinical Oncology web site, Last accessed December 28, 2012, http://www.asco.org/ASCOv2/Practice+%26+Guidelines/Guidelines/Clinical+Practice+Guidelines/American+Society+of+Clinical+Oncology+Provisional+Clinical+Opinion%3A+The+Integration+of+Palliative+Care+into+Standard+Oncology+Care.

17. "CVS Caremark's view of Oncology Drug Management" by Troyen Brennan, *Specialty Pharmacy Times*, May 2011, Last accessed December 28, 2012, http://specialty.pharmacytimes.com/publications/specialty-pharmacy-times/2011/May-2011/CVS-Caremarks-View-of-Specialty-Pharmacy-Management

18. "CVS Caremark's View of Oncology Drug Management, Part 2", by Kirby Eng, *Specialty Pharmacy Times*, published online December 5, 2011, Last accessed December 28, 2012, http://specialty.pharmacytimes.com/publications/specialty-pharmacy-times/2011/November-2011/CVS-Caremarks-View-of-Oncology-Drug-Management-Part-2

19. "2011 Medical Pharmacy and Oncology Trend Report™ ", ICORE Healthcare, a division of Magellan Health, Last accessed December 28, 2012, http://www.icorehealthcare.com/icore-resources/trend-report.aspx, Page 28

20. "Impact on health plan cancer drug costs in different delivery models", by Dawn Holcombe, Rex Force, Kerry Bradley, Joe Conoshenti, and Keith Huff, *Journal of Managed Care Medicine*, a publication of the National Association of Managed Care Physicians, Vol. 15, Number 4, Pages 69 – 80. http://www.namcp.org/Journals/JMCM/Articles/15-4/PullDowns/Info%20Cancer-DrugCosts.htm

21. "NCCN Guidelines® & Clinical Resources, Permissions Requests", a web page on the home site of the National comprehensive Cancer Network, Last Accessed on December 28, 2012: http://www.nccn.org/about/permissions/

22. "Florida Blue launches oncology ACO", by Margaret Dick Tocknell, for Healthleaders Media, Published online May 14, 2012, Last Accessed December 28, 2012, http://www.healthleadersmedia.com/page-1/LED-280059/Florida-Blue-Launches-Oncology-ACO.

23. "Accountable Care Organizations come to oncology", by Tracey Reagan, published online at OncLive web site on October 17, 2012. Last Accessed December 28, 2012, http://www.onclive.com/publications/obtn/2012/september-2012/Accountable-Care-Organizations-Come-to-Oncology/1

24. "Total Cost of Cancer Care by Site of Service: Physician Office vs Outpatient Hospital ", published by Avalere Health, Inc., March 2012, Last accessed December 31, 2012, http://www.avalerehealth.net/news/2012-04-03_COA/Cost_of_Care.pdf

25. "Impact on health plan cancer drug costs in different delivery models", by Dawn Holcombe, Rex Force, Kerry Bradley, Joe Conoshenti, and Keith Huff, *Journal of Managed Care Medicine*, a publication of the National Association of Managed Care Physicians, Vol. 15, Number 4, Pages 69 – 80. http://www.namcp.org/Journals/JMCM/Articles/15-4/PullDowns/Info%20Cancer-DrugCosts.htm

26. "2010 Medical Injectables and Oncology Trend Report: First Edition™ ", ICORE Healthcare, a division of Magellan Health, Last accessed December 28, 2012, www.icorehealthcare.com/icore-resources/trend-report.aspx, Page 33 - 34

27. "2011 Medical Pharmacy and Oncology Trend Report™ ", ICORE Healthcare, a division of Magellan Health, Last accessed December 28, 2012, http://www.icorehealthcare.com/icore-resources/trend-report.aspx, Page 55-56.

28. "New Study Finds that 10% of Cancer Patients Abandoned Oral Anti-Cancer Drugs", Press Release by Erica Garland of Avalere Health Inc., May 18, 2011, Last accessed December 31, 2012, http://www.avalerehealth.net/wm/show.php?c=&id=881

29. "Growth And Dispersion Of Accountable Care Organizations: June 2012 Update, by David Muhlestein, Andrew Croshaw, Tom Merrill, and Christian Peña, Center For Accountable Care Intelligence, Levitt Partners, Last Accessed December 31, 2012, http://leavittpartners.com/wp-content/uploads/2012/06/Growth-and-Dispersion-of-ACOs-June-2012-Update.pdf

30. "Medical Home and ACO", a web page on the home web site of the Community Oncology Alliance, last accessed December 31, 2012, http://www.communityoncology.org/site/medical-home-aco.htm.

31. "Total Cost of Cancer Care by Site of Service: Physician Office vs Outpatient Hospital ", published by Avalere Health, Inc., March 2012, Last accessed December 31, 2012, http://www.avalerehealth.net/news/2012-04-03_COA/Cost_of_Care.pdf

32. "Impact on health plan cancer drug costs in different delivery models", by Dawn Holcombe, Rex Force, Kerry Bradley, Joe Conoshenti, and Keith Huff, *Journal of Managed Care Medicine*, a publication of the National Association of Managed Care Physicians, Vol. 15, Number 4, Pages 69 – 80. http://www.namcp.org/Journals/JMCM/Articles/15-4/PullDowns/Info%20Cancer-DrugCosts.htm

33. Cornes P. The economic pressures for biosimilar drug use in cancer medicine. *Targ Oncol* 2012; 7 (Suppl): 57-67.

34. McCamish M, Woollett G. The state of the art in the development of biosimilars. *Clin Pharmacol Ther* 2012: 91: 405-417.

35. Schiestl M et al. Acceptable changes in quality attributes of glycosylated biopharmaceuticals. *Nat Biotechnol* 2011; 29: 310-312.

36. Veerport K, Mohler TM. A non-interventional study of biosimilar granulocyte colony-stimulating factor as prophylaxis for chemotherapy-induced neutropenia in a community oncology centre. *Ther Adv Med Oncol* 2012; 4: 289-293.

37. Aapro M. Biosimilars in oncology: current and future perspectives. *GaBI Journal* 2013; 2: 91-93.

38. Abraham I et al. Cost savings from anemia management with biosimilar epoetin alfa and increased access to targeted antineoplastic treatment: a simulation for the EU G5 countries. *Future Oncol* 2014, 10: 1599-1609.