

Alternate Sites of Care – Infusible Drugs

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Site-of-care access issues are not going away. While the historical business model has been good for hospitals and insurers, it has not been as good for consumers or plan sponsors. Many legacy health systems have strong brands, market presence and quality but high fixed costs and prices. Although this is not something people normally think about, risk is now driving many of the changes seen in the 2016–2017 market. Insurance fundamentals that supersede the ACA are driving changes seen in coverage, and at a more rapid pace each year, resulting from ACA impacts.

As a result, insurers and hospitals need to significantly change their cost structures. Nearly all health care organizations face an immediate need to reduce costs, driven by the pressure of value-based payment and consumer demand. Site of care represents one of the largest and easiest areas for cost reduction now. This white paper provides some key background on risk and site of care along with market impacts.

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INTRODUCTION

This white paper will briefly explore the commercial insurance market coverage policy shift to alternate sites of care (ASOCs), the underlying issues and resulting implications for key stakeholders around the use of biologic and specialty infusion drugs.

It's commonly thought that the primary factor driving patients into ASOCs was looming physician shortages. As a result, patients must look to alternate options and venues to meet their medical needs.¹ The physician shortage had been driving the growth to date in ASOCs such as retail convenience clinics and hospital ambulatory care clinics.

There is now, however, another important factor driving the increase in ASOC options: financial risk from insurance decisions resulting in medical policy changes. This white paper will examine that risk in the context of marketplace change like ASOCs. In addition, transferring risk to other stakeholders (physicians, patients) challenges the marketplace to develop different, efficient, high-quality, and low-cost alternatives to delivering healthcare in the traditional hospital setting.

ABOUT ASOCs

ASOCs refers to healthcare that is delivered in settings different from and generally less expensive than a hospital room, outpatient center or physician's office, such as an in-home setting, hospital outpatient department clinics, retail or convenience care clinics, urgent care clinics, various independent or corporate free-standing medical clinics and now, care delivered via telehealth.

Infusible drugs typically used in hospitals are covered under medical claims billing. Biologics, biotechnology-based or high-cost pharmaceuticals—collectively known as specialty drugs—can be covered under the pharmacy benefit, the medical benefit, or both, depending on the healthcare benefit plan sponsor's coverage policy required by the third party administrator or payer, e.g., Blue Cross, Cigna, etc. On average, up to 50% of specialty drugs, such as infusion products, are covered under the medical benefit.²

Technology has also played a role in the shift to ASOCs by bringing about rapid as well as significant improvements in the availability of a variety of drug formulations, methods of administration, and the ability to deliver care outside of the hospital and in non-acute settings of care, including the patient's home. Rheumatoid arthritis (RA) is just one disease state that has been affected by such changes and has benefited from improved biologic-based products that are available in different dose forms.

ASOCs Related to Reimbursement

As reimbursement rules have been adjusted since 2000, through contractual changes agreed upon by purchasers of care (individuals and employer groups), the ability to

consider the pros and cons of different sites of care and the related economics of risk has come into play. A number of new issues are being seen among the key stakeholders based upon their level of risk. In particular, as higher costs (risk) occur, there is an increasing trend toward mitigating that risk by looking at benefit design options that target stakeholder behaviors to lower that risk, such as ASOCs.

For the past several years, the infusion-product market has been moving from hospital-based care to ASOCs. As a result of high-cost and higher volume drugs such as rheumatology and oncology infusion products, manufacturers are increasingly being affected by the commercial insurance market's shift of medical coverage policies to lower-cost alternate sites or levels of care for infusion of specialty drugs.

FACTORS UNDERLYING THE SHIFT TO ASOCs

Risk Trends and the Commercial Insurance Sector

In order to address the now-significant trends associated with specialty drug spending from a payer or consumer perspective, it is critically important to be able to adeptly manage drug spending regardless of benefit design. Intentional aspects of benefit design also come into play. These factors are part of the risk-management strategy within the group health benefits program that includes medical, pharmacy, and other optional benefits (e.g., vision care, dental, legal, life insurance, etc.). Following is a brief explanation of how risk works within commercial health insurance programs.

Employee Benefits and Risk from an Insurance Perspective

Employee benefits, like healthcare, are defined as all forms of financial returns and tangible services and benefits employees receive as part of an employment relationship.³

Risk is defined as uncertainty with respect to possible loss. All types of potential losses associated with employee benefits are risks from the standpoint of an individual as well as a business. Loss is any decrease in value suffered. For example, a hospital bill for a patient receiving a drug infusion could result in a loss, because it would decrease the value of assets held by an individual or business.⁴ In this case, the loss would occur as a result of claims costs associated with an insurance benefit e.g., from the administration of an infusible drug.

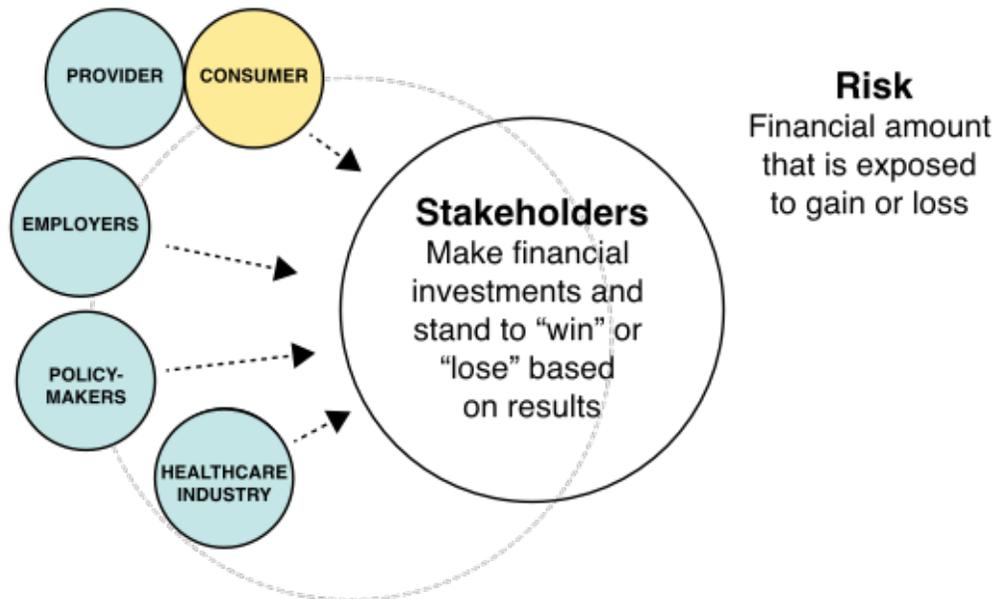
It follows, then, that insurance and health benefits are designed with a heavy emphasis on costs (risk) for health insurance programs covering employee benefits.

Stakeholders, Risk, and Care Cost Impact

Stakeholders that carry the greatest insurance risk have a more prominent role in decision-making, in terms of exposure to gains and losses, than those with a lower level of risk. The perception of the value of these decisions to each stakeholder determines who

receives the greatest attention from manufacturers (see Figure 1).

FIGURE 1 Stakeholders and Risk



Adapted from AMI’s presentation at AMCP October 2015: “Impact of Stakeholder Risk in Healthcare: Employers and Insurance,” and AMI work product, 2016.

The mix of stakeholders includes those who carry more insurance risk in today’s healthcare environment, such as consumers (patients) and providers (hospitals, physicians, pharmacies), those that tend to have a lower risk (health plans, insurance companies), and those in the industry (including pharmacy benefit managers and manufacturers) that generally take no risk.

Public and commercial payer pressures, combined with new benefit designs that demand a more engaged consumer have driven the shift to value-based payment models and connect payment to cost and quality standards. Because of method of administration and regulatory requirements, infusible specialty drugs have historically been included in care covered under a group medical plan and billed by a physician, clinic, or hospital. Therefore, all medical claims exposure has included the cost of drugs within the characteristics of risk for health coverage.

SEEKING VALUE: HEALTH PLAN EVOLUTION

Key to a medical insurance program is the benefit plan design and delivery of desired covered care in accordance with service site contracts. Methods to best manage benefit delivery of clinical services have also evolved in response to market demands and economic necessity arising from risk sharing. For example, incentives to cover infusions at

the lowest cost by setting of care has grown through medical policy at health plans, but not necessarily in all health insurance plans or areas of the country.

Market Convergence, Medical Groups, Hospitals, and Health Systems

Market change is a certainty, and site of care affects price differences for a variety of health care products or services provided to patients with traditional health plan or employer-sponsored insurance. Potential drivers of price differences by site of care aside from contractual differences include vertical integration (hospitals acquiring physician practices), and horizontal integration (hospitals acquiring other hospitals).⁵

CURRENT MARKET LANDSCAPE

Specialty Reimbursement Policy Fuels Alternative Sites

Rheumatology and oncology represent two major areas of specialty drug use today. In addition to the scientific and clinical expertise required to manage drugs in these highly managed categories, biologics require specialized approval processes and proper coding, and they impose substantial operational burdens on practices above and beyond those associated with other therapies.

Healthcare reform in general has encouraged the use of alternative settings and exploration into new types of financial or risk sharing arrangements. For example, some retail clinics provide primary care in retail pharmacy and grocery chains. What was originally a small number of these clinics focused on dealing with acute conditions has now developed into 2,800 primary care clinics that now address chronic conditions.⁶

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The practitioners and institutions adapting to the new reimbursement environment will be successful. For example, reclassification of inpatient units to independent medical units is part of the rapid growth in ASOCs of all types—this is a market response to change, thereby creating new opportunities for more cost-effective care.

Optimizing Care Site by Managing Specialty Drugs and the Medical Benefit

As is the case in many emerging areas of health care, definitions lag behind the changes in clinical or administrative practice. One current example linked to a care delivery site is medical benefit [drug] management (MBM) used by health plan sponsors.

MBM refers to the tactics and strategies to help control specialty drug spending for drugs that are specifically billed through a third party administrator or payer's medical benefit drug design. Drugs billed through the medical benefit are typically liquid or powder formulations requiring intravenous and injectable administration in a physician office, hospital outpatient clinic or ambulatory infusion center.⁷

Health care organizations succeed by standardizing processes, implementing best practices, managing care optimally, and applying a balance of clinical and business acumen. Today's tools for managing specialty drug spending under the medical benefit have not proven to be ideal. As a result of this need to carefully choose care sites, the use of ASOCs through medical policy offered an easier and successful way of lowering care costs.

SPECIFIC STAKEHOLDER (PATIENT, PROVIDER, PAYER) IMPACTS RELATED TO COVERAGE POLICIES THROUGH 2018

In 2017 and for the immediate future, companies that market and sell specialty pharmaceutical products should be aware that ASOC strategies will likely grow in prominence in the infusible marketplace. This is because ASOCs (1) optimize site of care financially, and (2) support the so-called Triple Aims of Healthcare by offering a lower cost, high-quality, and positive experience for consumers.

Simply put, to payers, this represents an opportunity to demonstrate their value in decreasing care costs while taking credit for promoting the Triple Aim goals.

Employers as health plan sponsors are also promoting the use of ASOCs in self-funded plans through their plan administration vendor, such as TPAs and PBMs. This trend influences traditional health plan medical policy as well as providers (health system or medical groups) who seek direct contracts with employers for their medical services.

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Common targeted categories include oncologic, dermatologic, and rheumatologic conditions that offer easy implementation of site change with significant cost savings to the plan or plan sponsor. In general, the only exceptions to this trend would be products whose administration demanded an acute care environment or patients with complications that preclude their use in an ASOC.

For new plan year implementations, bellwether events, such as United Healthcare/Optum and Anthem's updated coverage policies, have had an immediate impact on various infusion-based

products. These policies are a result of work done 12-18 months earlier in the employer benefit design timeline. For example, Anthem's shift in policy around site of care has already affected select products in a mid-Atlantic state as policies are renewed. It is expected that a number of additional products will be affected going forward as ASOCs expand. In other states or as other policies renew, the same promotion of "new" ASOC coverage by policy can be expected in 2017.

The specific role that ASOCs will play from national medical policy down to regional and local payer product access and specific contracting strategies will ultimately depend on the amount of risk others (patients and providers) are being forced to take or are willing to take. As a result, the impact on patients, provider hospitals or medical staff, and employers purchasing insurance in the commercial market will be swift.

In addition, PBMs have announced that a greater number of drugs are no longer considered preferred and will not be covered under the pharmacy benefit.⁸ Changes such as these can also cause site-of-care shifts based upon the contractual impact with a particular provider and/or site of care as well as the type of patient-specific financial risk exposure (deductible, coinsurance, and premium).

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Other employer plan sponsor resources are increasingly available now that influence medical policy or plan design, such as the National Employer Initiative on Biologic & Specialty Drugs (for one example of a resource, see www.specialtyrxtoolkit.com).

The care delivery and reimbursement pendulum is swinging back slowly toward greater simplicity and a differentiation based upon quality outcomes delivered at the patient level. This pendulum swing is not exclusive to specialty pharmaceuticals like RA drugs.

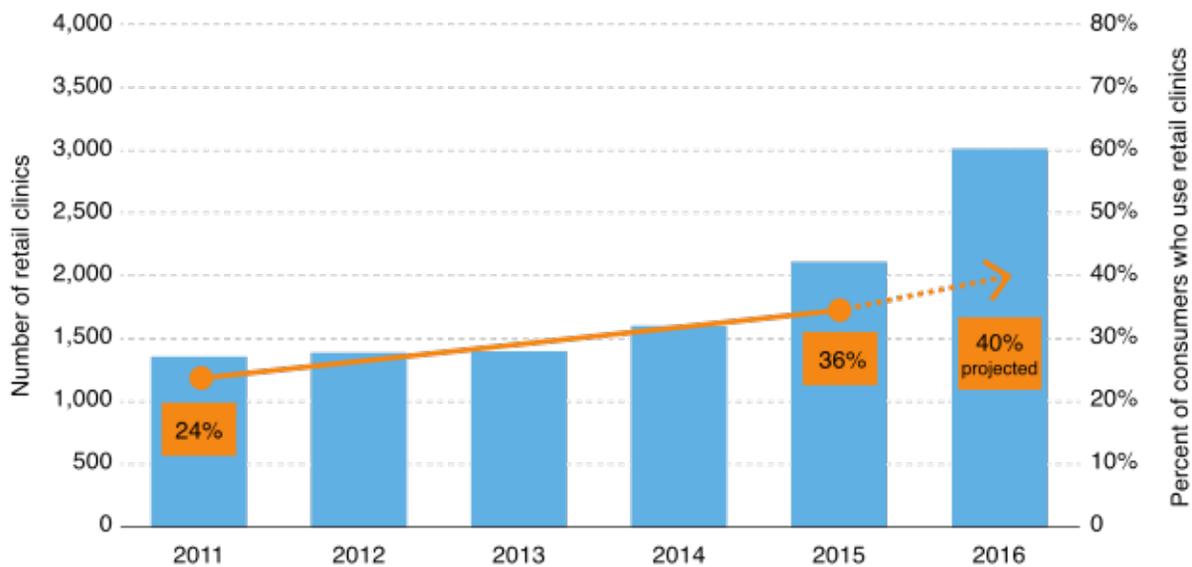
Shifts in risk and operational efficiency have led to the rapid growth in retail-based convenient care clinics throughout the United States. The result is a natural movement toward ASOCs as opposed to traditional hospitals and their ambulatory care settings. Similarly, the trend toward more local and home-based care has also been fueled by advances in health care providers' ability to offer more complex services to patients, including infusion treatments, in a wider variety of settings.

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Market growth in convenient care clinics and an increasing demand by patients seeking ASOCs began prior to, and has accelerated after, passage of the ACA. Those natural consumer market trends, coupled with payer benefit design shifts, have been intensified through marketing efforts by ASOCs to payers.

All of the above-mentioned factors have led to a decrease in the utilization of traditional hospital-owned sites of care that will likely drive a significant increase in the use of ASOCs through 2018. This is evidenced by rapid growth reported by the Convenient Care Association and repositioning by Walgreens and CVS Health as community care sites—they can legitimately state that they are more than just a pharmacy (see Figure 2).

FIGURE 2 Use of Retail Clinics is Increasing Along with the Number of Places for Treatment



Source: PwC Health Research Institute Consumer Survey and Convenient Care Association data.

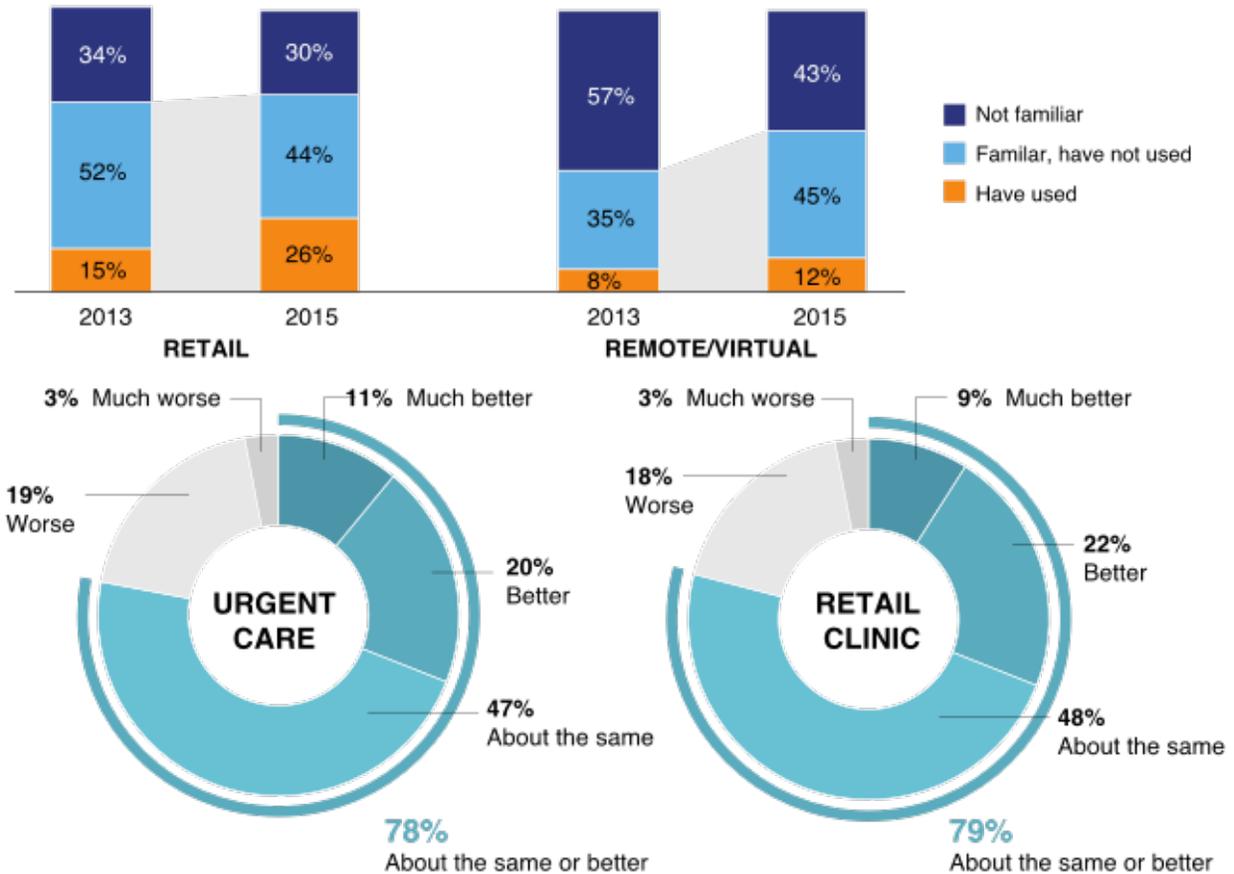
A recent Oliver Wyman national online survey of more than 2,000 individuals found that consumers’ awareness and use of ASOCs is on the rise. Consumers are showing no reluctance to use other sites besides their physician’s office or local hospital to receive care. This will have tremendous implications for the entire healthcare system, including pharma manufacturers who are experiencing reimbursement changes.

So as not to miss out on direct savings opportunities, employers have also grown on-site and near-site dedicated clinics to provide care services. Today, these sites are available not only for their employees, but they have expanded to family members and include the complete spectrum of primary care as well as infusions.

Hospitals and health systems are increasingly assuming the role of the contracted provider in those employer-owned on-site facilities through direct contracts. Purchasers of health care can attribute the successful use of ASOCs to the demonstrated positive impact on risk and value-based healthcare decision-making (see Figure 3).

FIGURE 3 Growing Consumer Acceptance of Retail and Urgent Care Clinics

Over the past two years, both familiarity and use of retail clinics and remote/virtual care has increased.



Most people who have used retail and urgent care options found the experience the same or better than a traditional site of care.

Source: Oliver Wyman, *The New Front Door to Healthcare is Here*, 2016.

PERSPECTIVE OF PATIENTS, PAYERS, AND PROVIDERS IN AN EXPANDING ASOC ENVIRONMENT

The shift to ASOCs will affect the key market stakeholders in different ways. The marketplace had undergone many subtle changes that began before the ACA, and they have only accelerated after its passage. The patient, payer and provider remain key players in terms of their impact on determining what actions can be taken vis-a-vis healthcare costs and delivery.

Patients

Consumers' willingness to use ASOCs will have tremendous implications for the entire healthcare system, including manufacturers, who are experiencing changes in reimbursement policies. As consumers are paying more of their health plan premium and experiencing higher out-of-pocket cost-sharing for all types of healthcare services, they will identify sites of care that will save them money. Cutting out the middlemen, which ASOC does to an extent, allows for lower costs to consumers and manufacturers, but also allows profits for payers as well as manufacturers.

Payers

Payers, reeling from the increasing costs of infusion drugs, are rapidly changing their medical policies for coverage of specialty drugs (including rheumatology drugs) for cost savings across the country. Payers are looking to shift patients into the lower cost sites of care. When asked about contracting/reimbursement strategies for the coming year in the EMD Serono, 2016 Specialty Digest survey of commercial health plans, 44% and 35% reported that they plan price renegotiations for home infusions and the outpatient hospital, respectively.⁹ Manufacturers need to consider having their field reimbursement staff proactively work with their clinical customers in shifting patients to the site of care for infusion products that will benefit both the patient and the provider.

Providers

Under what circumstances do specialist providers see ASOCs as valuable? This tends to occur when they see that using ASOCs gives them better outcomes at a lower cost; their reimbursement profile changes along with their level of risk sharing. For home infusion and outpatient hospital providers (OHPs), reimbursement methods vary, with the majority of OHP payments made as a percentage of billed charges.⁹ As a result, determining the level of care required now has to incorporate reimbursement impacts on their patients as well as themselves. This represents an ongoing concern that needs to be addressed.

SUMMARY

Unlike many previous business cycles in healthcare, these changes are not temporary. ASOC is not a cyclic phenomenon but the evolutionary result of market changes; independently owned clinics will improve their business while hospital-owned clinics will decrease. For legacy insurance and health systems, quality of care, market presence and reputation are important strengths that will continue to be differentiating factors. ASOC shifting is just one symptom for market change related to reimbursement and key stakeholder behaviors.

Although contracting with national payers may continue, it's necessary to also appreciate that because risks can shift at the local level, national product coverage decisions can be usurped by local providers who have shared risk or at-risk contracts.

Recently, the National Business Group on Health (NBGH), conducted a member survey on the issue of specialty drugs... the survey showed: “Employers’ focus in 2017 is shifting away from plan design to optimizing how health care is accessed and delivered.”¹⁰

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Customer-facing field and home office professionals will need updated knowledge and skills to successfully interact with risk-holding shareholders in a fluid, fragmented, and constantly changing marketplace. These are complex problems with no clear answers— so finding opportunities to change, like using ASOCs, is a strategic imperative for the key stakeholders.

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WEB RESOURCE

www.specialtyrxtoolkit.com, Managing Specialty Benefits, Employer Checklist for Site of Care.

GLOSSARY

Alternate Site Provider: may be part of an existing healthcare system that is integrated with traditional settings. The purpose of these providers is not to have a 'new front door' but to provide the patient with a better experience and higher satisfaction and lower costs. Examples include infusion clinics, home health care, birthing centers, ambulatory surgery centers, and urgent care centers. (*Healthcare Finance News*; available at <http://www.healthcarefinancenews.com/news/use-alternative-care-sites-has-swelled-significantly-survey-finds>)

Ambulatory clinic: outpatient setting that provides health services or acute care services that include infusion. (The Medical Dictionary; available at <http://www.medical-dictionary.thefreedictionary.com/>)

Brown bagging: infused or injected medications are shipped directly to the patient, who takes them to a medical office to be administered. (Advisory Board; available at <http://bit.ly/2c7LLGM>.)

Denial of claim: the refusal of an insurance company or carrier to honor a request by an individual (or his or her provider) to pay for health care services obtained from a health care professional. (Available at: <http://www.healthinsurance.org/glossary>)

Employer-based infusion suite: located in an employer clinic, which offers health services, including infusion, at the workplace. Each clinic varies based on the nature of the employer and the workforce. (The Alliance, Employers Moving Health Care Forward; available at <http://www.the-alliance.org/>)

Home infusion: setting where a patient receives infusion therapy in their home, with the help of experienced home infusion nurses and pharmacists. (Coram, CVS Specialty Infusion Services)

Hospital infusion clinic: dedicated setting in hospital for patients who require outpatient infusion therapy for short- or long-term treatment. (Froedtert Hospital Infusion Clinic; available at <http://www.froedtert.com/infusion-clinic>)

Hospital outpatient: the traditional location in which drugs have been infused, and are often commingled with chemotherapy, blood transfusions, biologics and fluids for rehydration. (Mark Huizenga Systems Consulting LLC, 3 Most Common Types of Infusion Centers; available at <http://www.huizenga-consulting.com/blog/bid/27519/3-Most-Common-Types-of-Infusion-Centers>)

Infusion clinic: independently owned infusion centers where it is often convenient for patients to receive intravenous therapies 7 days a week/365 days a year in a comfortable setting. (Access Market Intelligence; data on file)

Medical benefit management: MBM helps to control specialty drug spending, and provides care and services across disease states and sites of care, especially triaging patients in conjunction with the payor(s) to deliver optimal outcomes. (Medical Benefit Drug Management Webinar/Survey Findings Report, April 1, 2016. Access Market Intelligence, LLC; data on file)

Medical benefit plan: benefits are specific areas of plan coverages, i.e., outpatient visits, hospitalization, etc., that make up the range of medical services that a payer markets to its subscribers. Also, a contractual agreement, specified Evidence of Coverage, determining covered services provided by insurers to members. (Bureau of Labor Statistics, Definition of Health Insurance Terms; available at <http://www.bls.gov/ncs/ebs/sp/healthterms.pdf>)

Payer/third party administrator: organizations with expertise and capability to administer all or a portion of the claims process. (The Managed Care Contracting Handbook, 2nd Edition)

Pharmacy benefit plan: plan sponsors offer a pharmacy program as part of their benefit plan for members that offer a wide variety of high-quality, effective generic and brand-name drugs. (Pharmaceutical Care Management Association [PCMA]; available at <http://www.pcmanet.org/2016-press-releases/>)

Physician practice Infusion center: physician delivers infusion services directly to patients in a familiar and supportive setting, allowing the physician to direct the administration of the treatment rather than referring patients to the hospital. (The Rheumatologist; available at <http://www.the-rheumatologist.org/article/managing-an-in-office-infusion-practice/>)

Plan sponsor: the entity that is legally responsible for the financial risk associated with the offer of health insurance coverage for their covered members. This could be a state licensed health plan or a self-funded employer plan under federal law. (U.S. Department of Labor, Meeting Your Fiduciary Responsibilities; available at <https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/publications/meetingyourfiduciaryresponsibilities.pdf>)

Prior approval/authorization: a cost-containment procedure that requires a prescriber to obtain permission to prescribe a medication prior to prescribing it. (Center for Health Transformation; available at <http://www.centerforhealthtransformation.org/>)

Purchaser/payer: the entity that not only pays the premium, but also controls the dollar spend before paying it to the provider (care, service or product). Included in the category of purchasers or payers are patients, businesses and managed care organizations. (The Managed Care Contracting Handbook, 2nd Edition)

Retail pharmacy clinic: medical clinics located in pharmacies, grocery stores, and “big box” stores, such as Target, that provide care for simple acute conditions typically delivered by a nurse practitioner. Increasingly, retail clinics are considering offering infusion services as well. (RAND Corporation; available at <http://www.rand.org/health/feature/retail-clinics.html>)

Self administration: a type of plan usually present in larger companies where the employer itself collects premiums from enrollees and takes on the responsibility of paying employees’ and dependents’ medical claims. These employers can contract for insurance services such as enrollment, claims processing, and provider networks with a third party administrator, or they can be self-administered. (Available at www.healthcare.gov/glossary)

Specialty drugs: high-cost prescription medications used to treat complex, chronic conditions like rheumatoid arthritis, multiple sclerosis, and cancer. The drugs may come in different formulations for use and require other special handling or tracking requirements. (Available at www.healthinsurance.org/glossary)

Specialty pharmacy: focuses on high-cost, high-touch medication therapy for patients with complex disease states. Medications in specialty pharmacy range from oral to cutting-edge injectable and biologic products. The disease states treated range from cancer, multiple sclerosis and rheumatoid arthritis to rare genetic conditions. (American Pharmacists Association; available at <http://www.pharmacist.com/>)

Third party administrator: a Third Party Administrator (TPA) is an organization that processes insurance claims or certain aspects of employee benefit plans for a separate entity. This can be viewed as “outsourcing” the administration of the claims processing, since the TPA is performing a task traditionally handled by the company providing the insurance or the company itself. Often, in the case of insurance claims, a TPA handles the claim processing for an employer that self-insures its employees. In this case, the

employer is acting as an insurance company and underwrites the risk. (Zane Benefits, Small Business Employee Benefits and HR Blog; available at <https://www.zanebenefits.com/blog/topic/exchange>)

Unbundled services: includes carve-out programs such as pharmacy. A Third Party Administrator approach allows employers to select the services (unbundled) required from multiple providers, with their coordination being managed by the TPA. (Business Insurance; available at <http://www.businessinsurance.com/article/99999999/NEWS050101/110809926/decision-must-be-made-on-administrative-approach>)

Value-based benefit design: comprehensively addresses the way health **benefits** are structured and utilized by employees. Its focus is broader than just the insurance design and includes other types of incentives. (NBCH Value-Based Purchasing Guide; available at <http://www.nbch.org/vbpguide>)

White bagging: the method of delivery by which physician-administered drugs are dispensed by a specialty pharmacy (SP) for a specific patient, shipped to the physician for administration, and generally paid under the pharmacy benefit rather than the medical benefit. (Kantar Health Blog; available at <http://blog.kantarhealth.com/blog/gordon-goehenauer/2014/03/28/the-evolving-use-of-white-bagging-in-oncology>)