



URAC Specialty Pharmacy White Paper

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# The Patient-Centered Outgrowth of Specialty Pharmacy

*Why Patient Management Strategies Are Critical to 21st Century Providers*

## Introduction

Specialty drugs have seen a tremendous boost within the pharmaceutical marketplace over the past several years. Consider some of the telltale statistics – after a 22 percent increase in market share from 2008 to 2010, and the requisition of a \$50 billion chunk, or roughly 17 percent, of total pharmaceutical revenues, specialty drugs are poised for a long run of expansion and increased utilization. The way the industry sees it, based on the latest metrics, studies and forecasts, healthcare has seen but a glimpse of what the specialty market has in store. According to future-trending reports, specialty drugs will account for the majority of new drug approvals in coming years, and they will consume approximately 40 percent of a health plan's drug spending by 2020.

This rapid expansion has set the key stakeholders in the specialty arena – health plans, manufacturers, pharmacies, and others parties like employers – into a state of evolution in the face of an exciting, if uncertain, future. Like any other interconnected system, the changes that are taking place within the specialty subset are influenced by the overarching trends in the healthcare system. As the health reform bill places patient-centered care into the lexicon – and into the practical, everyday practices – of healthcare professionals far and wide (e.g., patient-centered medical home, accountable care organizations), the state of pharmaceutical management has followed suit. And as certain health and disease indices of the U.S. population grow in commonality as well as complexity, the management of drug regimens has perhaps never been more important. And this is particularly true for a class of drugs that deals with two crucial factors in healthcare today; foremost, specialty drugs are expensive, and they

are generally used to treat patients with difficult conditions marked by co-morbidities, tough therapeutic regimens, and high rates of recidivism.

This is where specialty pharmacies enter the picture. These high-touch, full-service providers serve a unique and highly specialized role within healthcare delivery. By focusing on the targeted task of specialty drug distribution, delivery and ultimately utilization and adherence, the prevalence of – and services offered by – specialty drug pharmacies are on the uptick as well. In this case, the increasing rates with which health plans are requiring the use of specialty pharmacies is perhaps only the second most telling trend behind the importance that health plans place on quality-proving factors for specialty pharmacies – namely accreditation. Not only do payers want to use a specialist, but they want to make sure that the specialist is held to careful, comprehensive and evidence-based industry standards.

This document illustrates the rapid growth of the specialty pharmaceutical industry and the roles that key stakeholders play along the continuum. The document identifies why specialty pharmacy is on an upward trend, paying particular attention to the emerging areas of patient-centered care, care coordination and patient management. In addition, the document sheds light on the contributing factors amid the current states of health and healthcare in the U.S. to show why specialty drugs, specialty pharmacies and the thorough programs that focus on holistic care are on the rise, and, ultimately, here to stay. Finally, the document explores the myriad benefits of accreditation – and how leading accreditation programs are ushering in the charge in this new era of special – and specialty – change.

## Background

Assessing the sheer number of new drugs on the market and the overhead picture of total utilization figures, the latest numbers and statistics clearly demonstrate that specialty pharmaceuticals are rapidly moving forward on a train of upstream momentum. This class of drugs, defined by high costs and, among other characteristics, the need for special handling requirements, comprises more than 16 percent of national pharmaceutical spending in the U.S. today, according to the latest research<sup>1</sup>. Additional data, which conveys the small-but-robust nature of the specialty sector, reveals that more than two-thirds (70%) of the changes in drug cost and utilization over the past year are attributable to specialty drugs. The specific therapeutic usage of specialty drugs, along with what is often unrivaled stature as therapeutic options in today's market, gives them impressive leverage in the healthcare marketplace.

Indeed, over the past decade-plus, specialty drugs have steadily encroached on the total share of the national pharmaceutical market (Reuters), the world's largest, which boasts total annual spending of \$307 billion<sup>2</sup>. In the two-year period from 2008 to 2010, specialty drug spend increased from 12 percent of total market share in 2008 to 14 percent in 2009, followed by a 13 percent year-to-year jump that has pushed the dollar amount to more than 16 percent of overall drug revenue in 2010<sup>3</sup> – overall, a 22 percent increase in three years. Research shows that this steady expansion may be a mere sign of things to come. Healthcare consulting firm IMS Health predicts that global revenues in the specialty sector will surpass \$160 billion in 2013<sup>4</sup>. Meanwhile, a recent ExpressScripts report predicts that the total drug spend devoted to specialty meds will reach a full 40 percent of total share by 2014<sup>5</sup>, or what amounts to an estimated \$123 billion in today's dollars.

With specialty drug spending on the rise, the systems that create, harness and deliver these high-touch pharmaceuticals – manufacturers, payers, providers, pharmacies and other stakeholders – are in a state of evolution as well. More than 700 new specialty drugs are currently in development, and the expected stream of specialty approvals is making stakeholders reconsider and redesign their channels of delivery and access. Presently there are multiple access channels available for end users, ranging from physician providers, facility providers

(e.g., inpatient and outpatient), ancillary providers like home infusion companies, and the wide swath of pharmacy providers, which includes retail, mail services and specialty pharmacy. During a time when payers are placing a keener focus on patient-centered care and patient management<sup>6</sup>, and when physicians may be reluctant to purchase high-cost drugs for which they, potentially, won't be reimbursed, full-service delivery and distribution specialists are offering a sought-after value proposition, one that combines services geared to promote appropriate use and to supply patient education, therapy management and adherence programs.

In addition to an increasing preference for patient management, payers are seeing a change in their internal processes as well. According to research, a large portion of spending growth has taken place in the medical benefit<sup>7</sup>. Between 2005 and 2008, several drug categories saw significant increase in medical drug spend, increasing by approximately 327% for multiple sclerosis, 204% for hypertension, and 57% for inflammatory conditions. Overall, roughly 55% of total drug spend occurs on the medical portion of the benefit. Yet the proportion of specialty drugs available through the pharmacy benefit is on the rise. Research suggests that specialty trend under the pharmacy benefit will expand by approximately 27% in each of the next three years<sup>8</sup>. Spending on inflammatory conditions, multiple sclerosis and cancer will continue to make up approximately two-thirds of drug spend within the pharmacy benefit over the next three years.

While the overriding factors behind the division between medical and pharmacy benefit classification are somewhat nebulous, a look at one predominant historical trend sheds a hint of light on the future position of these benefits as the industry moves forward. Traditionally, drugs that require an extra layer of care, such as infusions for hemophilia, are likely to exist within a plan's medical benefit. Conversely, drugs requiring less intensive interventions, such as oral medication and other self-administered agents, fall under the umbrella of the pharmacy benefit<sup>9</sup>. With an increasing number of disease categories that are host to therapeutic options that cross this historical divide – multiple sclerosis, for instance, which is treated through both oral and IV medications – industry reports reveal an unprecedented cohesion between medical and pharmacy benefits, with more than 70 percent of health plans reportedly mandating that their internal pharmacy departments track such drugs across both benefits<sup>10</sup>.

Of course, manufacturers are integral to the growth of specialty pharmacy. Today, drug manufacturers are producing more drugs that fit within the confines of the specialty category than ever. With the recent torrent of personalized

<b>Comparing Pharmacy Benefit vs. Medical Benefit</b>	
<b>Pharmacy Benefit</b>	<b>Medical Benefit</b>
Drugs intended to be self-administered	Drugs administered by healthcare professionals
Self-administered subcutaneous drugs; injectables; oral meds	Infusions; most MI injections; some subcutaneous drugs; intra-articular drugs
50% of specialty drugs	50% of specialty drugs
45% of specialty spend	55% of specialty spend

*Source: AIS Health "Specialty Pharmacies Continue to Garner Broad Health Care Interest" Specialty Pharmacy News Atlantic Information Services, Inc. October 2007 and Express Scripts Inc. 2010 Drug Trend Report. 2011; 28.*

drugs, biologics and biosimilars, the sheer number of specialty drugs available is in an upward swing, continuing to take over a greater share of new drugs entering the market. In 2010, the Food and Drug Administration approved 27 new drugs (15 new molecular entities, six biologics, six therapeutic biologics) and granted 33 new indications for medication that was already on the market. Specialty drugs boasted high percentages in both categories – seizing 56 percent (15 out of 27) of the approved drugs and nearly half of the new indications (16 out of 33)<sup>11</sup>. In terms of cost and utilization, three disease categories comprised the bulk of the attention. Specialty drugs manufactured for the treatment of rheumatoid arthritis, multiple sclerosis and cancer led the way in 2010, though the cost and use of specialty drugs for hemophilia, metabolic disorders and pulmonary arterial hypertension saw sizable year-to-year advancements as well.

While this class of drugs has long been characterized by injectable medicines, manufacturing advancements continue to create opportunities for easier administration, notably in the realm of oral medication. This is best encapsulated by Gilenya™, the first oral drug for the treatment of multiple sclerosis, which was approved in the fourth quarter of 2010. In early 2011, a rash of oral treatments have gained approval for conditions that include thyroid cancer, prostate cancer and RA. While advanced delivery continues to gain ground, traditional models also remain strong. Other specialty drugs of note that have crossed the approval line since 2010 include

new infusions for rheumatoid arthritis, prostate cancer and breast cancer (Actemra®, Jevtana® and Halaven®, respectively), as well as the MS injectable Ampyra®, which has already gained a strong foothold within the patient population.

All of this begs the question: Why is the prevalence of specialty drugs on the rise? And more importantly: What does this portend for suppliers in this increasingly complex marketplace? As mentioned above, advances in clinical research and delivery capabilities are one major reason. Yet there is more to the trend than newfound manufacturing prowess. Indeed, a healthcare professional does not need to look far to see another prominent driver. The average patient (read: individual) in the U.S. today has a 50 percent chance of presenting with at least one chronic illness, according to national data<sup>12</sup>. Approximately one in five adults, or 50 million people, has been diagnosed with arthritis; as the nation’s leading cause of disability it limits the daily activity of more than 20 million per year. Cancer prevalence in 2007 (the latest year for which comprehensive data exists) fell just shy of 12 million cases, according to the American Cancer Society<sup>13</sup>. Roughly 400,000 people are affected by MS<sup>14</sup>. And the growing obesity epidemic has taken its toll on the health of the population. One-third of American adults are obese (CDC), and the condition is considered a contributing factor to nearly every chronic illness on the shelf<sup>15</sup>.

The rise of chronic illness, coupled with the increasing sophistication of the pharmaceutical sector to pinpoint more efficacious and personalized drugs, has created a dynamic environment for the growth of the specialty sector on the whole.

**Biologics and Biosimilars: Charting the Difference**

**Biologics**

**What Are They?** Medicinal products made from living organisms

**Trends:** Many biologics under development are oncology drugs. Other examples include epotin, insulin, growth hormone, filgrastim.

**Biosimilars**

**What Are They?** As the FDA describes it, biosimilars “are biological prescription drugs that are demonstrated to be ‘highly similar’ (biosimilar) to or ‘interchangeable’ with an FDA-approved biological product.”

**Trends:** Biosimilars are not generics; they undergo clinical trials before going to market; a key to their usage growth will be physician comfort with their quality and efficacy.

## Why Specialty Pharmacy?

Before examining the diverse benefits of full-service specialty pharmacies, we should define the subject at hand – that is, specialty drugs and specialty pharmacies. Unlike other facets of healthcare, there is no hard and fast definition of specialty pharmacy. Depending on the payer, provider or organization you check in with, the definition can vary, although a handful of attributes remain the same across these different channels.

In general, specialty drugs are marked by two attributes: cost and complexity. Specialty drugs are expensive, and because of their delicate nature (limited shelf life, steady temperatures, etc.) they require special handling, administration, unique inventory management, a high level of patient monitoring and more intense support than conventional therapies. The intravenous prostate cancer drug Provenge®, for example, requires specific premedication before therapy and close monitoring of patients with cardiac or pulmonary conditions throughout the course of treatment. Other drugs, like the class of injectable medications engineered to treat multiple

sclerosis, must adhere to precise handling methods as they traverse the healthcare landscape from manufacturer to medical provider to patient.

As part of its Part D drug benefit, the Centers for Medicare and Medicaid Services (CMS) defines a specialty drug as one that costs more than \$600 per month. Other industry data derived from a large survey of health plans suggests that the specialty threshold is reached at a minimum price point of \$1,200 per month<sup>16</sup>. Pushing the definition past price, one large healthcare data company and a network of industry trade associations have settled on a variety of attributes to define a specialty drug. According to their specifications, to be considered “specialty” a drug must fall into five of the following eight categories:

- A drug that treats specific, mainly chronic, and often rare conditions.
- A drug whose usage initiates with a specialist.
- A drug typically not administered orally.
- A drug that requires special handling.
- A drug whose use involves unique distribution and administration channels, such as special distribution management and specialized paperwork.
- A drug that is costly, ranging from \$6,000-\$750,000 per year.
- A drug whose usage requires high degrees of patient management, like increased supervision of counseling.
- A drug whose use results in patients requiring reimbursement assistance.<sup>17</sup>

When it comes to the *who* of specialty pharmacy and the huge dollar amounts and patient outcomes at stake, the picture grows a bit more complex. In its most effective incarnation, specialty pharmacy consists of a high-touch comprehensive care system of pharmacological care wherein patients receive expert therapy management and support tailored to their individual needs (see Section IV below). Because these institutions stand at the crux of drug delivery and patient management, full-service specialty pharmacies are in a prime position to effect positive outcomes and boost quality measures that ultimately impact financial spend and resource utilization, not to mention patient wellness. (More on this below.)

As stated above, the rise of chronic conditions combined with prosperous technological advancements in the pharmaceutical industry have resulted in rapid expansion in

### Causes of Poor Compliance – and a Glance at Potential Revenue Capture

Poor adherence to medication is a huge cost drain. When a patient fails to follow a treatment regimen for the duration of the drug therapy as outlined by a healthcare professional, the consequence is an annual tab of \$290 billion to the healthcare system. The wellness costs are equally distressing for nonadherent patient populations. And when it comes to high-cost specialty drugs, the cost proposition on both sides climbs even higher. What causes nonadherence? Understanding the cause can help identify solutions. Research suggests that the top five reasons for nonadherence to specialty drugs are:

#### Complex, large molecule and biologic drugs

- Difficult to manufacture and shorter shelf life.
- Generally limited inventory.
- All routes of administration including orals, self-injectables, etc.
- High cost/unit.

#### Requires special handling and services

- A high level of patient support – more education and monitoring than traditional pharmaceuticals.
- Often requires periodic lab results, diagnostic tests or REMs reporting.

#### Target small population rare and chronic diseases

- High medical cost for the patient.
- Patients require education on disease, drug regimen and administration.

#### High Cost results in Reimbursement Challenges

- Co-pay Programs and Patient Assistance Programs.
- Covered by prescription and /or medical benefit.

the specialty sector. For what are often delicate and comorbid populations, where interventions can mean the difference between an adherent, low-cost outcome and a non-adherent, high-cost readmission or relapse, specialty pharmacy provides the comprehensive patient management techniques that can spell the difference between the two outcomes – providing benefits to employers, manufacturers, payers and, of course, patients. Let's take a look at some of the key issues at stake within this larger specialty arena.

### Medication Adherence

The widespread prevalence of medication nonadherence – that is, simply put, a patient's inability, refusal or outright neglect of maintaining a proper course of drug therapy as recommended by a physician or other healthcare provider – is a national problem that taxes the healthcare system to the tune of billions of dollars per year in preventable costs and results in suboptimal health outcomes. A 2009 study from the New England Healthcare Institute (NEHI) estimates that medication nonadherence is attributable to \$290 billion in avoidable healthcare costs<sup>18</sup>. Consider some other sobering statistics about the medication adherence dilemma:

- As many as 40 percent of patients do not adhere to their treatment regimens.
- Up to 69 percent of medication-related hospital admissions are caused by poor medication adherence (at a cost upward of \$100 billion/year).
- As many as 25 percent of *total* hospital and nursing home admissions are the result of poor adherence.
- A patient with substandard adherence has three times as many doctor visits per year and averages \$2,000 more per year in costs than adherent patients. (Center for Health Transformation)
- In the subset of patients with chronic disease, roughly 50 percent fail to take their medication as directed.<sup>19</sup>

With the rapid growth of chronic illness, this final bullet point induces extra cause for alarm. As NEHI executive director Valerie Fleishman said at the time of the study's release: "This is a growing problem fueled by a growing population – those with preventable chronic illnesses." And this is an area, according to research, where specialty pharmacy can deliver robust outcomes through their quality-focused, patient-centered interventions. A recent IMS Health study investigated the compliance rates of patient

taking specialty drugs, as these drugs were delivered across four unique options – standard retail pharmacy, specialty pharmacy provider, standard mail and an aggregate category of all other delivery options. The specialty pharmacy segment outperformed its competing delivery channels in each of the four drug categories, outpacing the drug compliance rates of standard retail pharmacies by an average of 9%. In this study, the specialty pharmacies achieved an average adherence rate of 87%, vs. 78% in the standard retail sector<sup>20</sup>. As a 2010 Center for Health Transformation study insists: "As we search for strategies and solutions geared toward improving patient adherence to prescription drug therapy, it is imperative to involve pharmacists...pharmacists, as the medication experts, have demonstrated the ability to inform, problem-solve and provide performance support directly to and with patients."<sup>21</sup> Specialty pharmacies inform, problem-solve and provide support. Yet they do so to a far more intensive degree.

### Defining Specialty Pharmaceuticals

Specialty drugs may vary from one payer's definition to the next, but they generally adhere to a consistent set of rules. While the IMS Health list nudges closer to a true definition of specialty drugs, below is a primer on this unique class of therapeutics:

- 1. Poor results.** If a drug fails to meet the expectations of the patient, he or she will be more likely to discontinue use. This is true for medicines that have a longer lead-in time to achieve efficacy.
- 2. Difficult administration or results.** Some specialty drugs have drastic side effects that may discourage use, while others are inherently difficult or onerous to administer, such as infusions or injectables.
- 3. High costs.** By definition, specialty drugs are expensive. When a patient faces a high premium or co-pay, it may result in discontinued usage.
- 4. Symptom control.** Some conditions are asymptomatic and others, like multiple sclerosis, go through periods of remission. The lack of symptoms may lead a patient to discontinue the use of a drug.
- 5. Co-morbid conditions.** Where there is more than one condition present, the success of medication adherence dwindles. Depression, for example, is a common cause of poor compliance with the treatment plan.<sup>22</sup>

### Case Study

In the IMS Health study that compared the delivery channels of specific specialty drugs to the effectiveness of medication adherence (see above), the financial trend rings loud and clear. Comparing the continued use of two specialty drugs over a one-year period, the study found that specialty pharmacies delivered a 20 percent boost in medication compliance rate – resulting, in one drug category, in a \$9,000 boost in revenue for the provider per patient per year.<sup>23</sup>

### Length of Stay

Long considered a marker of quality in the acute care setting, length of stay has clear implications for the payer setting

as well. Namely, reduced length of stay correlates to lower spend. In addition, the decreased length of stay lessens the chances of a patient acquiring a nosocomial infection, an event that accounts for one in six reimbursement claims<sup>24</sup> and adds up to \$45 billion in additional hospital costs per year<sup>25</sup>. In the post-reform era, quality measures such as these have become financial testaments. In July 2011 Medicaid began denying payments to hospitals for the fiscal repercussions of certain hospital-acquired infections. With the right delivery channels in place, common specialty pharmaceuticals like infusion therapy can be administered in a patient's home, reducing the risk of hospital-acquired infections and increasing the patient's quality of life – all while decreasing costs to the healthcare system.

### Readmissions

Another marker of healthcare quality, readmissions are being put on the punitive financial block in the same way as length of stay. Starting in 2012, providers will be penalized for cases of avoidable readmissions for certain disease states, such as pneumonia and congestive heart failure. According to federal data, one in five Medicare patients are readmitted to the hospital within 30 days of the initial discharge. Within a year, that number jumps to more than 56 percent of patients. All told, preventable readmissions account for more than \$17 billion in annual added costs to Medicare<sup>26</sup>. One of the primary drivers of readmissions is medication misuse or mismanagement. Medication nonadherence is the cause of up to 25 percent of hospital and nursing home readmissions. Greater emphasis on patient management, including a medication compliance system, is an effective way to keep patients healthy and keep healthcare dollars in the pockets of payers – and with incentivized care rapidly arriving, in the pockets of providers as well.

### Return to Work

Employers have a fiscal stake in the area of specialty pharmacy – in more ways than one. When it comes to the administration of highly expensive drugs, it is wise for the employer to want to ensure their health plan providers are supplying their patients with full-service support tools. With improper drug handling, litigation is a threat to employers. The integration of pharmacy management and return to work

programs is another trend in the overarching movement toward patient-centered care that undergirds the important role of the pharmacist in disease and disability management. In the spring of 2011, CIGNA decided to supplement its disability management team with a pharmacist to “identify prescription-related trends and strategies to help people stay at work or to be successful in returning to work from disability,” according to a news release from the national insurance provider. According to Mark Marsters, Senior Vice President of CIGNA's Group Operations: “When looking at the array of tools available to help people prevent disability or return to work from a disabling injury or illness, prescription medication often plays a very important role.”<sup>27</sup> With the top 10 percent of disability cases accounting for more than half of total medical and disability costs<sup>28</sup>, the financial stakes are raised skyward for employers and insurance companies alike.

## The Benefits of Full-Service Specialty Pharmacy

When it comes to modern specialty pharmacy, like many other movements in healthcare, the trend is edging toward patient-centered care. As the sections above show, comprehensive patient management can result in a number of benefits that are beneficial to the various stakeholders involved. The full spectrum of patient-centered care offered by industry-leading specialty pharmacies target the quality measures mentioned above (among others) that are of great import to the pharmacy's fellow stakeholders in the vast pharmacy arena, from manufacturers to providers to payers. As the specialty sector pushes forward, with new drugs and more delivery channels than ever before, the emergent focus on quality has taken hold as well, becoming, by some respects, an ingrained part of payer models.

Indeed, one large study<sup>29</sup> of the nation's health plans reveals the extent to which these payers, including commercial and federal institutions, are incorporating dynamic specialty pharmacy functioning into their everyday models. The list of trends below reveals a clear message: A specialty pharmacy without established, adaptable, patient-centered operations is becoming a relic of the past. Looking at some of the study's major takeaways, here's an outlook of specialty pharmacy and specialty pharmaceuticals from the vantage point of national health plans.

**Prevalence of specialty pharmacy use.** The data shows that the vast majority of payers are currently using specialty pharmacies to deliver and distribute their drugs, and to manage the patient population utilizing these expensive therapeutics. According to the study, 88% of health plans have contracted with at least one specialty pharmacy provider. Just 7% of health plans manage their specialty drugs on their own.

**Mandatory use of specialty pharmacies.** Every health plan has its own rules over drug administration, but many health plans require some specialty drugs to be channeled through specialty pharmacy providers. This can vary for each payer and can depend on a specific specialty drug or a class of drugs. The majority of payers, however, require the delivery and distribution of drugs via specialty pharmacies for at least one main therapy division – Medicaid leads the way, with 71% of its plans requiring at least one therapy category to go through a specialty pharmacy; additionally, 64% of Medicare Advantage Prescription Drugs plans meet the same requirements, as do 59% of commercial plans. What follows are the 10 most common therapy categories for which health plans require the use of specialty pharmacy:

- Growth hormone disorders.
- Hepatitis C.
- Multiple sclerosis (injectable).
- Psoriasis.
- Rheumatoid arthritis/Crohn's Disease.
- Hemophilia factor.
- MS (oral).
- Oncology (oral).
- MS (intravenous).

Top services provided by specialty pharmacies. By and large, health plans appreciate the comprehensive patient management techniques offered up by full-service specialty pharmacies. Among the most sought-after services, attributes of quality management are of the most importance – giving a patient round-the-clock access to a pharmacist and/or registered nurse ranks as one of the top services provided, as does the implementation of comprehensive drug adherence programs. Patient education is another top attribute. When it comes to everyday practice, there are some things that health plans are more satisfied with than others. Two of the top four qualities concern a pharmacy's commitment to patient management. The full four are:

- Direct distribution of drugs to patients or physician.
- Coordination of reimbursement and eligibility.
- All-day access to a healthcare professional.
- Appropriate drug use.

**The good and bad of therapy management.** While most specialty pharmacies offer some type of therapy management service for specific disease categories, less than one-third (30%) of payers report utilizing these programs. Yet the patient-centered approaches that health plans reportedly seek (see above) suggest that therapy management programs, which seek to improve adherence, manage dosing and limit unwarranted use, offer untapped benefits in the form of improved patient outcomes, reduced waste and cost-savings. And indeed, a closer look at the data reaffirms this. While the overall utilization of therapy management programs is on the low side, the goals that health plans reported to seek through these programs once again illustrates the desire for better patient management. Across the top five most-used therapy management programs, health plans are in search of adherence and optimal dosage more commonly than other factors.

Most-desired outcomes produced by specialty pharmacies. As part of the Serono survey, health plans were asked what outcomes they most wanted to see out of the specialty pharmacies with which they interacted. Once again, patient-centered elements played a major part in the results, with two of the top three attributes involving quality management. The top three results that health plans want their specialty pharmacies to achieve are:

- A decrease in inappropriate utilization.
- A reduction in drug acquisition costs.
- An enhancement to adherence and persistency.

Tying these results in to Section II above, there is a clear intermesh between the ultimate goals of payers and the overarching elements that are defining quality healthcare in today's environment.

**Accreditation makes a difference.** The increased desire for discrete quality management strategies are a good marker of the shift toward better coordinated care, and this industrywide movement is cemented by payers' preference that specialty pharmacies achieve third-party accreditation

as a way to confirm their commitment to quality, cost containment and proper utilization. According to the Serono survey: “Healthcare purchasers are increasingly requesting that a specialty pharmacy become accredited by an independent third party organization to validate the pharmacy’s commitment to quality management, patient safety and monitoring, and prescriber and consumer communications.” In the eyes of industry leaders, URAC’s accreditation programs are considered the premier choice, accounting for almost two-thirds (64%) of the votes for which program payers deem “most important type of SPP third-party accreditation.”

### A Closer Look at Accreditation

It could be said that the industrywide push for accreditation is an organic outgrowth of the myriad trends swirling around the arena of specialty pharmacy – the increase in specialty drug production, utilization and costs; the shift in business models; the interconnected risk areas affecting payers and employers; and the incontrovertible proof that specialty drugs (and distribution and delivery channels) are not only here to stay but are transforming into a larger slice of pharmaceutical activities on a daily basis. The elements contributing to the growth of specialty pharmacy attest to it, and – what is perhaps the most telling sign of both specialty pharmacy’s latest and most influential coming-of-age sequence as well as its staying power – the financial arm of the process (i.e., payers) want to work with pharmacies that are serious about providing the level of care that the high-touch industry demands.

When it comes to accreditation, and the quality measures that accreditation can achieve for pharmacies, health plans, manufacturers and other stakeholders, it is worth looking at the standards of an accreditation body to see how the diverse pieces of the puzzle fit together. To illustrate the full-service elements that accreditation necessitates for specialty pharmacies, we take a look at some of the patient-centered standards from number-one ranked accrediting body URAC. As background, the URAC standards Specialty Pharmacy Accreditation cover a broad range of services, drug handling, operations management, and patient management. The four primary elements of the specialty drug accreditation, each

of which contains their own quality-laden standards (the number of which are in parentheses), are:

- Customer Service, Communications and Disclosure (13)
- Specialty Drug Management (5)
- Pharmacy Operations (15)
- Patient Management (22)

To stay true to the scope of this white paper, the fourth category in the bullet list above is where we will provide concrete examples of standards. (For the sake of brevity, the standards presented below are abbreviated; full standards are available [www.urac.org](http://www.urac.org).) Providing a closer look at what the URAC standards in patient management necessitate of a participating organization, we offer four examples of standards contained within the Patient Management category. As the examples show, the onus rests on patient-centered quality measures.

#### **Examples:**

#### **Patient Management (Standard) 2 – Program Criteria and Consumer-Centered Approach Patient Management Principles**

Programs that offer patient management services must include:

- Access to patient-specific and individualized services or sets of services to the patient;
- Patient-centered approach based on the best available science and demonstrated practices;
- A process to document patients’ management in a central location, such as a consumer/patient record;
- A process to effectively communicate to the prescriber and other healthcare providers involved in the management of the patient; and
- Strategies and interventions to optimize appropriate therapeutic outcomes for patients through improved medication use based on available information; and
- Support for patient advocacy and empowerment of self administration of drugs.

#### **Patient Management (Standard) 3 – Additional Criteria**

Services offered through the patient management program should:

- Be developed under the supervision of the clinical oversight body;

- Be provided in accordance with the third party payer's coverage policies;
- Include target population specifications;
- Include initial assessment of appropriate and/or inappropriate drugs;
- Include education concerning side effects, drug interactions, food/drug interaction, safe disposal and other safety precautions, such as handling and
- Include the coordinated development of a care/service plan;
- Monitor and promote medication adherence;
- Minimize the incidence of adverse events;
- Optimize therapeutic outcomes by promoting continuity of care during all patient care transitions and facilitates collaboration among all the patient's health care providers;
- Promote referrals when appropriate to other health care providers; and
- Include accommodation of language differences.

## Patient Management (Standard) 10 – Coordination of Care

The organization is able to coordinate care for targeted individuals with care management plans. Coordination may include one or more of the following:

- Establishing processes that allow appropriate sharing and communication of patient information among health care providers who have a need to know (such processes should be able to identify those practitioners who need to have access to this information); or
- Enhancing the effectiveness of patient management providers through appropriate use of information technology and other communication tools; or
- Providing a capability that allows one provider to refer patients to another; and
- Coordination of care that includes:
  - Activities describing what should occur, such as a care plan;
  - Identification of who will provide the service by provider type and care management program; and
  - Transition of care based on patient's needs.

## Patient Management (Standard) 11 – Informed Decision Making with Patients

The organization implements policies and procedures that address the counseling and education of patients, which

should address the following:

- Self-management and effective use of available clinical and educational resources with individual patients related to their medications; and
- Counseling and education related to medication:
  - Proper use;
  - Timely administration or intake;
  - Side effects;
  - Contraindications;
  - Safety precautions;
  - Reconciliation, such as multiple medications;
  - Disposal;
  - Storage; and
  - Concurrent use of over-the-counter medication, if provided by the patient.

## The Future of Specialty Pharmacy

The future looks bright for specialty pharmacy. As the statistics and industry sentiments presented above display, the trend is moving in a rapid direction forward, creating opportunities for providers to capture an evolving market. How big of an opportunity is there? Let's explore the growth areas, as presented by industry data.

Specialty drugs as a portion of the pharmacy benefit will rise precipitously. Data suggests that the share of specialty drugs comprising a plan's pharmacy benefit will increase by 27 percent each year over the next three years.<sup>30</sup>

Accordingly, member spend on specialty drugs will skyrocket. With increased access to specialty drugs, annual member costs will leap by a sheer 105 percent between 2010 and 2013 under the pharmacy benefit alone. In dollar terms, that means a jump from \$129.98 in 2010 to a projected \$266.03 in just three years.<sup>30</sup>

The lion's share of specialty utilization will remain with the big three: rheumatoid arthritis (and other autoimmune diseases), multiple sclerosis and cancer. From now until 2013, these three classes will continue to account for two-thirds of specialty drug spend.<sup>31</sup>

Specialty drugs will account for 40 percent of spending by 2020. Should the financial and usage trends continue as they are currently, the specialty class will comprise two out of every five dollars spent within a health plan's pharmacy spend.<sup>32</sup>

Finally, the use of accredited, patient-centered care will rise. Surveying payers, the Serono industry report asked its audience to rate the effectiveness of the top programs or services that helped their organization “achieve its overall specialty pharmacy management goals.” What came in at the top of the list? The contracted use of specialty pharmacy providers for self-administered agents. This strategy of trusting the distribution and management of high-cost and high-touch drugs with quality-driven organizations ranked as the fifth-rated strategy in 2008 and the fourth-rated strategy in 2009<sup>33</sup>. The same report found that two out of the top three strategies that payers plan to implement within the next 12 months deal with therapy management: the top-ranked strategy for health plans is the implementation of oncology management programs; the third-ranked strategy is the coordination of therapy management programs with specialty pharmacies<sup>34</sup>.

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