Specialty Pharmacy Initiative

- Phase I Discovery & U.S. Environmental Scan

- A Summary of Primary Research Findings & Highlights from Eight Key Stakeholders

- An Index of & Links to all Secondary Research
Note about Citations or References Regarding This Report

Requests to cite total aggregate findings or segment-specific information are welcome and will be considered on a case-by-case basis. Please direct your inquiries to Janna Crittendon at janna.crittendon@jcconsultinggroup.com. Additional contact information is provided on the back cover of this report. Copies of this Summary Report also are available in an Adobe PDF format.

Note about Specialty Pharmacy References

This report contains a wide variety of references to the topic, specialty pharmacy. Since no universally-accepted definition for specialty pharmacy nor its service components currently exists, we have been deliberate to keep all references and terms precisely as mentioned by each participant during each outreach interview.

About JC Consulting Group, Inc.

JC Consulting Group, Inc., (JCCG) is a privately-held healthcare strategy and communications firm with offices in Boston and Washington, DC. Founded in 2002 by Janna Crittendon, a veteran strategist and issues management counselor with experience in six health care settings, JCCG works at the critical intersection of health policy, health outcomes and business strategy. Assignments typically are multi-stakeholder in scope and relate to new technology, innovation and value proposition development. Executive-level clients range from across the Private and Public Sectors and influence the design and delivery of health care in the U.S.
As authors of this Summary Report and on behalf of the Foundation for Managed Care Pharmacy leaders, we wish to give special recognition and thanks to a number of people. Without their generous contributions of time, information, perspectives and always cooperative spirits, this work would not be possible:

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Confidential

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About FMCP

Overview
Established in 1990, the Foundation for Managed Care Pharmacy (FMCP) is a 501(c)3 non-profit charitable trust focused on research, education and philanthropic endeavors that are closely affiliated with the Academy of Managed Care Pharmacy (AMCP).

FMCP’s Mission
FMCP helps people optimize medication therapy through the generation and dissemination of new knowledge.

FMCP’s Passion
FMCP is dedicated to helping people get the most from their pharmacy benefit, leading to happier, healthier lives.

FMCP’s Value Proposition
- FMCP is an unbiased, credible source of information that can be utilized by consumers, payers, providers of pharmacy benefits and providers of care to obtain needed medications through the pharmacy benefit.
- FMCP’s research and educational efforts assist AMCP members and other healthcare professionals to stay current.
- FMCP serves to enhance the image of managed care pharmacy to the public, demonstrating the value of managed care pharmacy in improving health care.
- As a national foundation, FMCP has the ability to pool the resources of and partner with those who care about managed care pharmacy in order to ensure research and education efforts continue.

2007–2010 Key Strategic Imperatives
1. Research: Establish FMCP as a thought leader organization and “go to” organization that supports and conducts objective managed care pharmacy-related research.
2. Education: Translate and disseminate research findings and other key topics so that others can maximize opportunities for optimal patient care and best possible professional practice.
3. Finance: Ensure financial sustainability and growth to meet our mission.
4. Philanthropic Support: Position the Foundation to become a significant philanthropic resource that supports the advancement of healthcare for all people.
5. People: Achieve exemplary governance, leadership and staff performance.
6. Communications: Enhance recognition and understanding of the Foundation and its mission through strong branding, marketing, and high-quality communications.
2009 Research & Education Initiatives

1) Value-Based Healthcare: The Role of Pharmaceuticals
   - Evidence
     - Provide a Format for collection of evidence – AMCP Format for Formulary Submissions; (revision underway with the inclusion of specialty pharmacy)
     - Train healthcare professionals to analyze evidence
   - Adherence
     - Raise awareness of the importance of Adherence & Persistency among employers, payers and patients
   - Pharmacy Benefit Literacy
     - “Top 10 Pharmacy Benefit Management Questions” list for employers to help them educate their employees about how to optimize their medications
   - Strategic Leadership Forum – February 2009
     - Assemble healthcare leaders to advance the use of value-based thinking and identify research topics

2) Specialty Pharmacy
   - Specialty Pharmacy Project to identify critical elements of, needs and solutions for Specialty Pharmacy Management challenges

3) Healthcare Leadership
   - Summer internships in managed care pharmacy and a "best project" scholarship
   - National P&T student competition
     - Scholarships awarded to top three schools
In February 2009, FMCP assembled a special Governing Board/Task Force of pharmacists and healthcare executives to discuss priorities in the growing field of specialty pharmacy—and what role the Foundation for Managed Care Pharmacy could play. They agreed that the umbrella goal of this work should be:

- To conduct research and educational activities regarding access, affordability and adherence to life-saving medications that will help people live happier, healthier lives.

In addition, they agreed that any Foundation-sponsored project supporting this umbrella goal must be actionable, user-friendly and provide clear information to patients and the key stakeholders involved in specialty pharmacy care.

Four priority objectives/areas of interest were identified:

1) To gain consensus nationally on the language, meanings of terminology and references to the Specialty Pharmacy field.

2) To assess benefit design, care delivery methods and service-level specifics with annual tracking/monitoring to analyze what is most beneficial and what needs require professional clinician attention or a focus via new product development or benefit design.

3) To examine the incentives, services and fees associated with service-level specifics and product access, in order to help payers and other key stakeholders understand their impact on care delivery and optimizing patients’ health outcomes, functional status and quality of life.

4) To assemble information on the specialty pipeline in a directory/inventory format and interpret the implications of the availability of new technology, including companion diagnostics, to patients, payers and government agencies, with a frequency to be determined. Where possible, interpretation would be stakeholder-specific.

When JC Consulting Group, Inc. (JCCG) was approached to support this project, we recommended that a formal discovery and research process be conducted, to provide FMCP with a market-driven, baseline foundation of information. Not only did we believe that priorities should be validated, we also felt that specific needs and direction for particular projects should come from the target stakeholder groups themselves.
In order to assess the greatest needs and provide the Foundation with market-driven, actionable recommendations, JCCG consultants undertook two types of research:

1) **Primary Research**, consisting of two key components:
   a) Two small advisory group meetings with healthcare leaders whose roles require them to focus on specialty pharmacy in either healthcare delivery, patient advocacy work or as an employer or plan sponsor.
   b) Confidential, one-hour interviews with market leaders in eight stakeholder groups:

2) **Secondary Research**, consisting of literature and web-based searches of key medical/health journals, organizations focused on specialty pharmacy and companies providing products and services to patients. (A CD-ROM including an index of information, publications and other items relevant to this inquiry, is attached to the inside back cover of this report.)
Primary Research Objectives & Methodology

A. Objectives

1) Understand directionally, the macro and more defined, micro views about the issues, challenges and specifics are in specialty pharmacy today;

2) Gauge opinions, beliefs and perceptions about factors and obstacles affecting efficient, effective quality of care for this patient population (from the eight stakeholder groups); and

3) As appropriate, validate the original FMCP priority objectives and identify needs and potential approaches and solutions.

B. Methodology

Confidential, executive-level, one-hour interviews across eight target stakeholders. All information is de-identified, and therefore, not attributed to a particular respondent. (See the Discussion Guide on Page 23.)

Secondary Research Objectives & Methodology

A. Objectives

1) Conduct a thorough environmental scan of relevant literature sources and web-based companies, organizations and information sources associated with specialty pharmacy;

2) Understand and identify the most frequently mentioned specialty pharmacy topics, capture and catalog examples of publications and resource materials, websites or other information; and

3) Assess the quality, credibility and utility of available information.

B. Methodology

The key components of our Secondary Research were accomplished through classic key word searches, accessing leading peer-reviewed journals and reviewing websites and materials from leading companies and organizations involved with specialty pharmacy in the U.S. Under the direction and leadership of Michael B. McIntosh, Peter M. Penna, PharmD, and Rebecca M. Shanahan, JCCG was able to work with students at the University of Washington School of Pharmacy and Shanahan Capital Ventures, LLC, a specialty pharmacy-focused consulting firm working primarily in North America.
While most people think of specialty pharmacy drugs being used mostly in cancer treatment and in a few other well-known conditions, such as Multiple Sclerosis and Rheumatoid Arthritis, the array of health conditions dependent upon specialty pharmacy therapies also includes many others, such as Anemia, Cystic Fibrosis, Hemophilia, Hepatitis C, Human Growth Disorders, Neutropenia, and Psoriasis. In 2007, Shanahan Capital Ventures, LLC reported pharmacy spending for specialty drugs increased 12.3 percent, while utilization of specialty drugs increased 3.9 percent, which far exceeds the average overall national growth in prescription drug utilization of 1.9 percent.

The following Executive Summary is organized by FMCP Priority Items (see original assignment on Page 10) and highlights JCCG’s primary and secondary research activities. Since FMCP has identified patients and employer decision-makers as the primary audiences and initial beneficiaries of the Specialty Pharmacy Initiative, we have kept our focus on them, with secondary attention to the other stakeholders.

**FMCP Priority Items for the Specialty Pharmacy Initiative**

**Priority #1 – Definitions:** To gain consensus nationally on the language, meaning of terminology and references to the specialty pharmacy field.

Key Observations

Throughout our research, the lack of a common or universally-accepted definition of specialty pharmacy was cited often and observed to be a significant problem. In our primary research, it was either mentioned immediately or described as a factor or barrier to access, payment or delivery of care. Whether the examples came from employers and benefit consultants trying to complete requests for proposals (RFPs) for healthcare coverage (where comparisons of various vendors’ offerings are different), or clinicians confused by the way products are classified or made available through what channel and under what benefit design, or patient advocates explaining the constant challenges for patients accessing treatments and understanding benefit design that covers their drugs and treatments, the definitions issue is seen as central to easing the many complexities in this area of medicine and pharmacy.

Further, what qualifies a given medication or therapy to be classified as a specialty pharmaceutical is not clear. Most every entity, whether based in the Private or Public Sector, has some set of definitions or description of services it uses to operate and deliver care to its customers and patients. While the components or criteria may be similar, they are different for each channel or means by which a patient accesses the drug or treatment. This observation was common both in primary research discussions and throughout secondary research examination of public documents. Medicare’s Part D definition of specialty drugs is: *Any drug for which the negotiated price is $600 or more.*
Interestingly, with just one exception, JCCG’s request for sample definitions and/or descriptions of specialty pharmacy services of the health care delivery companies involved in this research was declined. URAC was the lone organization participating in our primary research to offer its definitions and grant permission for use or reference.

**URAC Specialty Pharmacy Standards**

| Specialty Drugs | Specialty drugs or pharmaceuticals usually require special handling, administration, unique inventory management, a high level of patient monitoring and more intense support than conventional therapies. They could include all routes of administration. |
| Specialty Pharmacy | Specialty pharmacy consists of a high touch, comprehensive care system of pharmalogical care wherein patients with chronic illnesses and complex disease states receive expert therapy management and support tailored to their individual needs. Medications that health plans and other payers classify as specialty pharmaceuticals may vary and evolve over time.

Specialty pharmacy incorporates synergistic core elements including:

- Delivery Channel: Designed to efficiently support the delivery of specialty medications direct to patient or physician;
- Business Model: Structured to support expert prescription fulfillment coupled with integrated services within a framework of rigid quality standards;
- Service Model: Crafted to achieve measurable improvements in clinical and financial outcomes through tailored patient-centric processes and activities; and
- Patient Satisfaction: By meeting/exceeding the clinical and administrative needs of high acuity patients in an environment of continuous quality improvement.

The specialty pharmacy is a provider of care and an agent of the patient. The specialty pharmacy is not the payer nor do they define the benefit. The payer may include a third party payer or a patient.
All other commercial entities, if willing to provide information, were willing to do so only if their identity was kept confidential. Many were unwilling to share information, describing their information as proprietary. Secondary research reveals bits and pieces of information about definitions and service components—with no consistency in definition, service components, service-level specifics or standards—and in many cases, information is incomplete or unavailable for anyone except providers and patients who have pre-authorized access.

Similarly, in our secondary research and analysis of publicly-available information (see Secondary Research Overview on Page 51 and CD-ROM located on the inside back cover), we found some common elements among the collection of over 300 documents and entries—but no consistent definition of specialty pharmacy or specifics associated with it.

To complicate matters further, we found five specific issues affecting definitions and terminology in specialty pharmacy:

1) Service-level specifics and offerings of specialty pharmacy providers, manufacturers and others involved in the delivery of such services, do not define service-levels in the same way;

2) Service levels appear to be built or influenced in at least five ways:
   a) by health condition;
   b) by a wrap-around service package;
   c) by drug-specific methods (not mandated);
   d) by U.S. FDA's Risk Evaluation and Mitigation Strategies (REMS) requirements; and
   e) by management guidelines and protocols requested by a particular customer contract.

3) Drug delivery mechanisms sometimes differ, which affects benefit design access and approvals. This means clinicians and other decision-makers must examine more than one class of medicines and under what benefit each option is covered, before writing the prescription for the patient;

4) Distribution (or dispensing) channels are not consistent across the industry, in product design, payment structure, or when distribution is limited to particular vendor sources or geography; or

5) The “special handling” requirements—whether storage or use-date related—and a host of other patient care delivery, monitoring and reporting needs—differ in scope on a product-by-product basis.

Validating or verifying service capabilities and what qualifies a company to be a specialty pharmacy provider becomes an issue for those seeking to assess care management options and create contracts with suppliers of these services.
Priority #2 – Benefit Design: To assess benefit design, care delivery methods and service-level specifics.

Key Observations

In our primary research, every stakeholder group reported considerable confusion—and in some cases, outrage—about a number of issues in how current benefit designs deal with specialty pharmacy drugs and therapies. Whether coverage is specified in the medical benefit or pharmacy benefit, confusion is “at an all-time high,” according to executives working both in market-leader companies and in not-for-profit groups. In one case, the specialty pharmacy industry was characterized as being a current-day version of the “Wild, Wild West.” Employers, plan sponsors and health plan leaders, in particular, expressed unanimously that they believe confusion about benefit design only adds fuel to their frustrations as they frantically try to create cost control mechanisms. How they make decisions about which patients should access these drugs—and under what circumstances—is very difficult.

Without common definitions or service standards, each company designs and delivers its own products and services. For patients and for employer decision-makers, maneuvering through the healthcare system channels involved with care plans and staying current with basics and best practices in each health condition is nearly impossible. All of these issues are seen by all stakeholders as key contributors to the universal concerns about the costs and affordability of specialty pharmacy products and services.

Over half of those interviewed for the primary research portion of this work expressed serious concerns about whether traditional pharmacy formulary tiers (where specialty products often are put into Tier 4, Tier 5, Tier 6 or other specialty designation with higher co-pays or average co-insurance of 33 percent) and other prior authorization procedures common in step-therapy approaches can ever work. Prior authorization processes are known to be costly to administer and increasingly irritating to providers trying to access particular therapies for their patients in a timely manner. In fact, many involved in our research are calling for entirely new benefit designs for specialty drugs and therapies. These cries are driven partly by the fatigue associated with the constant struggles to access and get reimbursed. Utilization review of patient-specific data also shows evidence of patients and providers “gaming the system,” to gain access to prescribed treatments at the lowest possible cost to them.

Decision-makers working in large employer settings, benefits consultants and health plan leaders all described the business-to-business climate in specialty pharmacy to be so complex that much more time and resources are needed to understand and manage daily patient care encounters and individual needs. In fact, everything is more time-consuming—from general administration, to claims management and utilization review, to clinician network management and exceptions and appeals, to assessing channels and the various vendors accountable for specific patients, to health outcomes analysis and reporting. Basic paperwork and documentation of codes for specialty pharmacy products and services can be problematic, as the quality and integrity of J-codes are both unclear and, in many cases, they are not specific enough for basic analysis. In addition, many interviewed for this project
expressed the need to better understand companion diagnostics and their impact on ancillary costs associated with decision-making related to specialty pharmacy drugs.

The issue of ongoing migration of some specialty pharmacy products and services from the medical benefit to the pharmacy benefit is met with mixed reviews. On one hand, data is better and available real-time on the pharmacy side. However, those advantages that are so important to clinicians, health plans and plan sponsors, present increasingly insurmountable disadvantages for patients—access, affordability and soaring out-of-pocket costs. Arguments are ongoing about which type of benefit provides for the best quality of care, special or wrap-around services, attention to side effects and managing individual patient needs, which often are seen to be as important as the drug therapy itself. (Wrap-around services and important clinical management and service-level specifics are addressed in Priority #3.)

Finally, the growing focus on medication compliance and adherence across the healthcare industry is an especially high priority in specialty pharmacy and the conditions most often associated with such therapies. Some leader-innovators are asking for value-based insurance design techniques, incentives and approaches to be tested in new benefit designs for health conditions that require specialty pharmacy. (More information on this important issue is provided in Priority #3.)

Priority #3 – Service-level Specifics: To examine the incentives, services and fees associated with service-level specifics and product access.

Key Observations

As we reported in Priority Item #1, service-level specifics differ across the provider community. The issues arising from the lack of common definitions or minimum service standards (see Priority #1) are numerous. Specialty pharmacy providers and others define, package, market, service and charge for specialty pharmacy services very differently. Service levels typically are defined by the wrap-around package of “high touch” services that come with a given medication, by the specific drug or patient need. Leaders in healthcare delivery repeatedly cited that the U.S. FDA’s REMS classification for certain drugs—or the complexity of the health condition itself—often dictates the drug-specific protocols.

All executives interviewed for this report expressed frustration over the lack of health outcomes data and information. Health plan leaders, employers and others said they don’t know how to evaluate specialty pharmacy services because they don’t feel that there is sufficient data to show the advantages and disadvantages of the various service options. Specialty pharmacy providers say they are hampered in this regard by the severe differences in data available from the medical and pharmacy benefits—as well as gaining access to a patient’s complete medical record. The total patient experience must be documented by integrating both—so many specialty pharmacy providers are moving to create systems that can do so. Efforts to track and understand patient compliance and adherence, in addition to reporting of side effects and efficacy of treatment and progress with care protocols, all are complicated by these data obstacles.
While none of those across the healthcare provider community was willing to share examples of fees or charges associated with their services, a number of them did share some information on the condition of anonymity. Examples follow:

**Example A: Service-level Specifics and Criteria**

<table>
<thead>
<tr>
<th>“Specialty” is not a U.S. FDA designation</th>
</tr>
</thead>
<tbody>
<tr>
<td>‣ Each PBM has its own criteria for defining and including drugs on their specialty lists. Some PBMs have multiple specialty lists they offer based on the size of the client.</td>
</tr>
<tr>
<td>‣ Company ABC has created a definition and criteria for a specialty drug designation and implemented a Specialty Advisory Board to apply the definition and criteria to new drugs.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Company ABC Specialty Pharmacy Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Specialty drugs” means those covered drugs that typically cost $500 or more per dose or $6,000 or more per year and have one or more of the following characteristics:</td>
</tr>
<tr>
<td>‣ Complex therapy for complex disease;</td>
</tr>
<tr>
<td>‣ Specialized patient training and coordination of care (services, supplies, or devices) required prior to therapy initiation and/or during therapy;</td>
</tr>
<tr>
<td>‣ Unique patient compliance and safety monitoring requirements;</td>
</tr>
<tr>
<td>‣ Unique requirements for handling, shipping and storage; and</td>
</tr>
<tr>
<td>‣ Potential for significant waste due to the high cost of the drug.</td>
</tr>
</tbody>
</table>

**NOTE:** Company ABC will categorize follow-on biologics or generic products as specialty drug if the innovator (brand) drug is a specialty drug.
### Example B: Service-level Specifics

<table>
<thead>
<tr>
<th>Baseline Services</th>
<th>High-touch Specialty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimal patient training and enlightenment regarding usage and proper handling other than traditional counseling. Telephonic injection training support.</td>
<td>High level of patient training regarding usage and proper handling. Address injection training needs with telephonic or home training.</td>
</tr>
<tr>
<td>Generally a one-time patient counseling session on first fill and availability to respond to questions as needed.</td>
<td>High-level and continued patient interactions beyond the initial dispensing process. Motivational interviewing and goal-setting with disease specific surveying with baseline and quarterly evaluations to set goals and monitor patient. Quality of life, disease progression, depression screening are examples of surveying for drug and disease-specific parameters.</td>
</tr>
<tr>
<td>Monthly patient contacts proactively addressing refills and availability to respond to questions as needed.</td>
<td>Targeted intervention determined by drug or disease state, may be additional contact points to review therapy, adverse events or monitoring (lab, physical evaluation, etc). Monthly patient contacts. Collection of labs or monitoring levels incorporated into care plan.</td>
</tr>
<tr>
<td>Basic level of communication with other health professionals.</td>
<td>Coordinate care with prescribers and other health care professionals including case management team of payor.</td>
</tr>
<tr>
<td>Patient compliance education is generally limited to counseling and labeling of the product.</td>
<td>Rigorous patient education is required often provided by nursing or pharmacist staff together with monitoring to assure optimal outcomes.</td>
</tr>
</tbody>
</table>
### Example C: Service-level Specifics

<table>
<thead>
<tr>
<th>I – Core Specialty Pharmacy Services*</th>
<th>II – Advanced care management (w/ options to define compliance)**</th>
<th>III – Home Infusion or Home Training***</th>
</tr>
</thead>
<tbody>
<tr>
<td>‣ Patient welcome, assessment and enrollment on-service</td>
<td>‣ Patient welcome, assessment and enrollment on-service</td>
<td>‣ Patient welcome, assessment and enrollment on-service</td>
</tr>
<tr>
<td>‣ Dispense to home or desired setting</td>
<td>‣ Nurse/Pharmacist pre-dispense compliance assessment and education call</td>
<td>‣ Schedule home infusion or patient training</td>
</tr>
<tr>
<td>‣ Benefit verification and coordination</td>
<td>‣ Mid-cycle compliance call/intervention</td>
<td>‣ Prepare resources and supplies to support home infusion or training</td>
</tr>
<tr>
<td>‣ Prior authorization as needed</td>
<td>‣ Dispense to home or desired setting</td>
<td>‣ Complete at-home treatment and assessment</td>
</tr>
<tr>
<td>‣ Patient Financial Counseling as needed</td>
<td>‣ Verify need for additional Rx prior to shipment*1</td>
<td>‣ Injection</td>
</tr>
<tr>
<td>‣ Shipment to support patient compliance</td>
<td>‣ Verify time and availability for shipment</td>
<td>‣ Infusion</td>
</tr>
<tr>
<td>‣ Reminder and follow-up calls as needed, based on patient fill</td>
<td>‣ Benefit verification and coordination</td>
<td>‣ Patient training</td>
</tr>
<tr>
<td></td>
<td>‣ Prior authorization as needed</td>
<td>‣ Other</td>
</tr>
<tr>
<td></td>
<td>‣ Patient Financial Counseling as needed</td>
<td>‣ Monitoring and follow-up</td>
</tr>
<tr>
<td></td>
<td>‣ Shipment to support patient compliance</td>
<td>‣ Documentations</td>
</tr>
<tr>
<td></td>
<td>‣ Ship only as verified to be needed per above in most contracts rather than to refill unnecessarily and provide a “false adherence”</td>
<td>‣ Schedule follow-up treatment</td>
</tr>
<tr>
<td></td>
<td>‣ Reminder and follow-up calls as needed</td>
<td>‣ Benefit verification and coordination</td>
</tr>
<tr>
<td></td>
<td>‣ Patient fill</td>
<td>‣ Prior authorization as needed</td>
</tr>
<tr>
<td></td>
<td>‣ Nurse and pharmacy support services as needed</td>
<td>‣ Certificate of medical necessity as needed</td>
</tr>
<tr>
<td></td>
<td>‣ Nurse and pharmacy support services as needed</td>
<td>‣ Patient Financial Counseling as needed</td>
</tr>
<tr>
<td></td>
<td></td>
<td>‣ Follow-up to support patient compliance</td>
</tr>
<tr>
<td></td>
<td></td>
<td>‣ Reminder and follow-up calls as needed based on patient fill</td>
</tr>
<tr>
<td></td>
<td></td>
<td>‣ Nurse and pharmacy support services as needed</td>
</tr>
</tbody>
</table>

* Level I – Wide range of chronic therapies. Can include some self-administered injectable although Level II is preferred. Most high cost oral products are seen as Level I.

** Level II – Company ABC prefers oral oncology products to be level II but that is not always possible. Self-administered, injectable products such as Humira®, Enbrel®, Betaseron® are typically Level II but we are under pressure and most contracts have a level I service offering unless they are Level III.

*** Level III – IVIG, Factor products

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*1 If metrics are not appropriately documented, this metric in contracts may not be appropriately defined. Company ABC prefers to be rewarded for managing patient inventory; therefore, do not ship product until a patient needs additional supply. This can appear as a compliance issue if metrics are not appropriately designed; metrics for this can vary.
Priority #3 – Service-level Specifics (continued)

Another factor in service-level specifics is the role of the physician. Since some medications covered under the medical benefit require reviews of patients’ health status, laboratory test information, or supervision during administration of the drug or therapy, the physician’s role is not questioned. In other cases, however, many health industry executives contend that pharmacists or nurse practitioners trained in the management of complex diseases are well-equipped to decide what is appropriate and monitor the patient during the appointment. Since physicians’ revenues are derived partially from services performed in association with specialty pharmacy treatments, most policy and other health care executives agree that physicians will work to protect their role and income accordingly.

Questions about the physician’s role in specialty pharmacy and the current lucrative financial incentives associated with “buy-and-bill” practices were raised by more than half of those we interviewed. Unsolicited, about one-third of those involved in our interviews expressed serious concerns about ethics in medical practice—with the patient and the payer (employer, plan sponsor or health plan) caught in the middle. Transparency in this regard is needed.

Priority #4 – Pipeline: To assemble information on the specialty pharmacy pipeline and interpret the implications of new technology, including companion diagnostics.

Key Observations

From all our sources—executive interviews, analysis of currently available public documents and manufacturer-provided information—the new drug pipeline is both a source of tremendous excitement and one of considerable concern. The sheer volume of new products renews hope that new treatment options for patients are coming. At the same time, manufacturers and payers alike worry about how to value, price and manage these new medicines. The annual estimated growth trajectory for new specialty drugs is 17 to 20 percent and in some cases, represents as much as 25 percent of the total drug budget. Keeping track of and understanding coming advances is a key element in planning and communicating cost-related information.

### Pipeline as of 2008*

<table>
<thead>
<tr>
<th>Type</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of biotechnology drugs</td>
<td>633</td>
</tr>
<tr>
<td>Oncology agents</td>
<td>254</td>
</tr>
<tr>
<td>‣ Oral chemotherapy agents</td>
<td>89</td>
</tr>
<tr>
<td>Infectious diseases</td>
<td>162</td>
</tr>
<tr>
<td>Autoimmune disorders</td>
<td>59</td>
</tr>
</tbody>
</table>

Source: Pharmaceutical Research and Manufacturers of America (PhRMA)
* The total number of new drugs in the pipeline is 3,462.
Payer decision-makers have numerous sources of pipeline information. They do not, however, have “pipeline interpreters.” Understanding the coming innovations and what they could mean for certain patient populations, new classes of medicines that open up new treatment pathways, along with powerful testing capabilities all are of significant interest to employers, plan sponsors and others trying to balance access with affordability. Cost remains a key consideration of all payers—who all struggle with how to make new drugs available to patients without such cost-shifting or cost-sharing that simply put them out of reach.

Since the science of many of these new therapies bring improved precision or are disease stage-specific, the ability to test patients in advance to ascertain their likelihood for therapeutic benefit is getting better. Given the per member per month (PMPM) or per member per year (PMPY) cost of specialty pharmacy agents, payers are clamoring for patient targeting and better pre-treatment testing capabilities. Therefore, the hope and perceived value of companion diagnostics for patients and payers is significant.

Assessing how new medications and therapeutic advances will alter the treatment landscape—and their impact on class-by-class reviews—is critically important. A credible, unbiased source or mechanism to provide such practical technology assessment information, e.g., “information about what this means for me, my employees/covered lives and my budget planning” is viewed by many to be one of the most important needs.
Discussion Guide

**FMCP Specialty Pharmacy Initiative Outreach Questions for All Stakeholders**

1) What do you see being the top three or four issues in Specialty Pharmacy care today?  
*(Please answer this as it relates to your stakeholder position—for clinicians, for health plans, for plan sponsors or for patients.)*

2) What are the longer-term issues and trends?

3) We have been told that Specialty Pharmacy is no longer considered a single entity; and that while some issues are similar across the therapeutic spectrum, that Oncology is being treated very differently from Multiple Sclerosis (MS), Rheumatoid Arthritis (RA) and other conditions. What is your position on this? Please elaborate.

4) On the Oncology front, are there examples of innovations that you believe represent a more patient-centric approach?

5) With more health plans adding specialty services, what do you believe will differentiate specialty pharmacy providers in the future?

6) How do you see the various distribution channels evolving?
   a) Oral  
   b) Infusion  
   c) Injection  
   d) Self-injection  
   e) Adjuvant therapies (such as anti-anemia, anti-nausea agents)  
   f) What is the role for retail pharmacy?

7) Do you see the migration of medical benefit to pharmacy benefit continuing? What are the potential gains vs. risks for patients and for the system?

8) How do you see the market reacting to the continuing cost pressure on patient care delivery?

9) What trends and/or barriers do you see in data collection? *(Please answer for the pharmacy benefit vs. the medical benefit.)*

10) What pending public policy changes do you believe will have the greatest impact on Specialty Pharmacy Delivery/Access?
## Accreditation Groups

<table>
<thead>
<tr>
<th>Organization</th>
<th>Representative(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Comprehensive Cancer Network (NCCN)</td>
<td>Elizabeth Danielson, Director, Payor Relations</td>
</tr>
<tr>
<td>National Committee on Quality Assurance (NCQA)</td>
<td>Greg Pawlson, MD, Executive Vice President</td>
</tr>
<tr>
<td>URAC</td>
<td>John DeSoto, Director, Pharmacy Markets; Jane Webster, Vice President of Marketing; John DuMoulin, Vice President, Government Relations and Product Development; Janice Anderson, Director of Pharmacy Programs; and Anthony Wisniewski, Senior Vice President, Strategic Development</td>
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## Employers

<table>
<thead>
<tr>
<th>Organization</th>
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<tbody>
<tr>
<td>Cisco Systems, Inc.</td>
<td>Pamela A. Hymel, MD, MPH, FACOEM, Senior Director Corporate Medical Programs and Integrated Health Benefits</td>
</tr>
<tr>
<td>The Procter &amp; Gamble Company</td>
<td>Sandra Morris, RN, MSN, CM, Senior Manager, Health Care Benefits Design</td>
</tr>
<tr>
<td>Whirlpool Corporation</td>
<td>Charles M. “Chris” McSwain, Director, Global Benefits; and Jan Butler, Senior Manager, US Benefits--Actives</td>
</tr>
<tr>
<td>National Business Coalition on Health</td>
<td>Andrew Webber, President and Chief Executive Officer; and Dennis White, Senior Vice President of Value-Based Purchasing</td>
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## Employer Benefits Consultants

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<tr>
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<tr>
<td>Buck Consultants, LLC</td>
<td>Michael S. Jacobs, RPh, National Clinical Practice Leader</td>
</tr>
<tr>
<td>Hewitt Associates, LLC</td>
<td>Kristin Begley, PharmD, Principal; and Kristi Passarelli, PharmD, Principal, Health Management Consulting Practice</td>
</tr>
<tr>
<td>Milliman, Inc.</td>
<td>Susan E. Pantely, FSA, MAAA, Principal &amp; Consulting Actuary, San Francisco; Frank Kopenski, ASA, MAAA, Principal &amp; Consulting Actuary, Milwaukee; Bruce Pyenson, FSA, MAAA, Principal &amp; Consulting Actuary, New York; and Brian Anderson, MBA, Consultant, San Diego</td>
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### Health Plans

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<tr>
<td>Aetna, Inc.</td>
<td>Duane H. Barnes, Division President – Aetna Pharmacy, Home Delivery &amp; Specialty, Aetna Pharmacy Management; Raechele M. McMahan, Program Development and Analytics, Aetna Pharmacy Management; and Edmund J. Pezalla, MD, MPH, National Medical Director and Chief Clinical Officer, Aetna Pharmacy Management</td>
</tr>
<tr>
<td>Kaiser Permanente</td>
<td>Sharon L. Levine, MD, Associate Executive Director, The Permanente Medical Group; Matthew T. Nye, PharmD, Director of Pharmacy Benefits and Business Development, Kaiser Permanente Health Plan, Inc.; and Murray N. Ross, PhD, Vice President, Kaiser Permanente Institute for Health Policy, Kaiser Foundation Health Plan, Inc.</td>
</tr>
<tr>
<td>United Health Group</td>
<td>Randy E. Falkenrath, Senior Vice President, Specialty Pharmacy and Business Development, United Health Pharmaceutical Solutions; and Lee N. Newcomer, MD, MHA, Senior Vice President and Business Leader – Oncology, United Healthcare</td>
</tr>
<tr>
<td>WellPoint, Inc.</td>
<td>Alan B. Rosenberg, MD, Vice President for Medical Policy, Technology Assessment and Credentialing Programs; and Brian T. Sweet, PharmD, Chief Pharmacy Officer</td>
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### Manufacturers

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<tr>
<th>Organization</th>
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<tr>
<td>Genentech, Inc.</td>
<td>Kathleen Kaa, Director of Product Managed Care Marketing</td>
</tr>
<tr>
<td>GlaxoSmithKline PLC</td>
<td>Joseph N. Kucharski, Account Vice President, Payer Markets; and Marci Mutti, Director of Reimbursement Policy</td>
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<tr>
<td>Teva Neuroscience, Inc.</td>
<td>Victor Morrison, Director of Regional Accounts</td>
</tr>
<tr>
<td>Wyeth Pharmaceuticals</td>
<td>Charles Schneider, Assistant Vice President, Health Care System Sales (Specialty); Mike Nuttal, Regional Account Director, Corporate Account Management (Specialty); Tom Koenig, Executive Director, Health Care Systems Brand Marketing (Specialty); and Kevin Cosgrove, Executive Director, Segment Marketing, Specialty and Retail Pharmacy</td>
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### Patient Advocacy Groups

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<tr>
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<tr>
<td>American Cancer Society</td>
<td>LaMar S. McGinnis, MD, Senior Medical Advisor and Liaison, Research and Cancer Control Science; Margaret K. Offermann, MD, PhD; Deputy Vice President, Research; and Victor G. Vogel, MD, MHS, FACP, National Vice President, Research</td>
</tr>
<tr>
<td>Arthritis Foundation</td>
<td>Bernadette O’Donoghue, Director of Advocacy and Public Policy</td>
</tr>
<tr>
<td>National Consumers League</td>
<td>Rebecca Burkholder, JD, Vice President for Health Policy</td>
</tr>
<tr>
<td>National Multiple Sclerosis Society</td>
<td>Kimberly Calder, MPS, Director of Insurance Initiatives; and Nicholas G. LaRocca, PhD, Vice President, Health Care Delivery and Policy Research</td>
</tr>
<tr>
<td>National Partnership for Women &amp; Families</td>
<td>Eva Powell, MSW, CPHQ, Director, Health Information Technology Project</td>
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### Professional Medical Societies

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<tr>
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<tr>
<td>American College of Rheumatology</td>
<td>Tiffany Schmidt, JD, MBA, Vice President for Socioeconomic Affairs; and Raymond Hong, MD, MBA; Assistant Professor of Medicine, University Hospitals Case Medical Center</td>
</tr>
<tr>
<td>American Academy of Neurology, PA</td>
<td>Katie M. Kuechenmeister, Manager of Medical Economics; and Lily Jung, MD, MMM, FAAN; Swedish Neuroscience Institute/Swedish Physicians Division</td>
</tr>
<tr>
<td>American Society of Clinical Oncologists (invited)</td>
<td>ASCO leaders deferred participation in this project.</td>
</tr>
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</table>
## Specialty Pharmacy Providers & Pharmacy Benefit Managers

<table>
<thead>
<tr>
<th>Organization</th>
<th>Representative(s)</th>
</tr>
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<tbody>
<tr>
<td>Accredo Health Group, a Medco company</td>
<td>Steven B. Russek, RPh, Vice President, Professional Practice and Chief Clinical Officer</td>
</tr>
<tr>
<td>AmerisourceBergen Corporation</td>
<td>Peyton R. Howell, President, Consulting Services &amp; Health Policy</td>
</tr>
<tr>
<td>CVS Caremark Corporation</td>
<td>Troyen A. Brennan, MD, Chief Medical Officer; and Albert R. Thigpen, Vice President of Industry Relations</td>
</tr>
<tr>
<td>Diplomat Pharmacy, Inc.</td>
<td>Philip R. Hagerman, President and Chief Executive Officer; and Athen A. Kaddis, PharmD, Vice President, Managed Markets, Diplomat Specialty Pharmacy, LLC</td>
</tr>
<tr>
<td>Express Scripts, Inc.</td>
<td>Steven B. Miller, MD, Chief Medical Officer; and Matthew C. Totterdale, Vice President, Specialty Pharmacy</td>
</tr>
<tr>
<td>MedImpact Healthcare Systems Inc.</td>
<td>Louis L. Brunetti, MD, JD, Senior Vice President and Chief Medical Officer; Richard G. Jay, PharmD, Vice President – Industry Relations; and Gary K. Rice, RPh, MS, MBA, Director – Specialty Clinical Management</td>
</tr>
<tr>
<td>Walgreens Health Services</td>
<td>Michael A. Nameth, RPh, MBA, Executive Vice President, Specialty Pharmacy</td>
</tr>
</tbody>
</table>
The Primary Research portion of this Phase I Discovery & U.S. Environmental Scan was undertaken from July through September of 2009. Thirty-three, one-hour interviews involving 62 executive decision-makers in leading global companies and national organizations across eight stakeholder groups were conducted. JCCG consultants wish to thank all who participated in this primary research for their time, interest in the topic and invaluable insights and examples. The question-by-question review follows:

### Question 1

What do you see being the top three or four issues in Specialty Pharmacy care today?

**Top Findings**

<table>
<thead>
<tr>
<th>Ranking</th>
<th>Mentions</th>
<th>Specialty Pharmacy Care Issues &amp; Trends</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>27</td>
<td>Cost &amp; OOP Burden</td>
</tr>
<tr>
<td>2 (tie)</td>
<td>10</td>
<td>Benefit Design/Coverage Confusion (Medical vs. Pharmacy) – plus Impact of Pipeline</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>Care Management Issues/Quality/Side Effect Management (Provider education deficits often mentioned with this)</td>
</tr>
<tr>
<td>3 (tie)</td>
<td>7</td>
<td>Distribution Channel Complexity</td>
</tr>
<tr>
<td>4 (tie)</td>
<td>6</td>
<td>Limited Distribution Channels &amp; Network Access</td>
</tr>
<tr>
<td></td>
<td>7</td>
<td>Patient’s Understanding/Education/Support</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>Off-label use issues</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>Patient Access Issues</td>
</tr>
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</table>

### Question 2

What are the longer-term issues and trends?

**Top Findings**

<table>
<thead>
<tr>
<th>Ranking</th>
<th>Mentions</th>
<th>Specialty Pharmacy Care Issues &amp; Trends*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>21</td>
<td>Cost &amp; OOP Burden/Prices for New Drugs</td>
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<tr>
<td>2</td>
<td>10</td>
<td>Availability of Bio-similars/generics</td>
</tr>
<tr>
<td>3 (tie)</td>
<td>7</td>
<td>Continuing Benefit Design Issues (Medical vs. Pharmacy)</td>
</tr>
<tr>
<td></td>
<td>7</td>
<td>Growth of the Pipeline</td>
</tr>
</tbody>
</table>

* A recurring point: Many mentions “same as current list – but intensity will ramp up or fade, depending on the outcome of health care reform” were made.

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**Reader’s Note:** For analytic purposes, we combined specialty pharmacy providers and pharmacy benefit managers into one group, because many of their services and offerings are similar.
Question 3

We have been told that Specialty Pharmacy is no longer considered a single entity; and that while some issues are similar across the therapeutic spectrum, that Oncology is being treated very differently from Multiple Sclerosis (MS), Rheumatoid Arthritis (RA) and other conditions. What is your position on this?

Most executives interviewed for this report indicated that specialty pharmacy has evolved to be very disease state-specific and in almost all cases, Oncology still is described as being handled differently from most other conditions. Even those citing the need to “avoid negative headlines at all cost” in cancer treatment decisions and the constant pressure to find ways to deal with rising out-of-pocket and co-insurance costs, say that oncology can’t remain sacred forever. Some are instituting care management approaches that are more focused on episodes of care—while others are constructing programs that are far more focused on the patient experience. Still others are experimenting with outcomes-based reimbursement across the continuum of care providers—taking aim directly, for example, at oncologists and others who do not follow clinical guidelines (for adults) and can’t document why. Since the amount and type of specialty pharmacy treatment options are growing rapidly across many health conditions, a much greater focus of energy and resources on specialty pharmacy is becoming much more standard.

Question 4

On the Oncology, MS or RA fronts, are there examples of innovations that you believe represent a more patient-centric approach?

Respondents struggled overall to answer this question. The majority said, “None comes to mind,” while a few described efforts now underway by some specialty pharmacy providers are more focused on what the individual patient’s needs are—thus, the hope that they would be the ones to chart the course for best practices in this regard. Executives with clinical management responsibilities indicated that the growing volume of biomarkers or companion diagnostics represents the best opportunity for patient-centered care.

Question 5

With more health plans adding specialty services, what do you believe will differentiate specialty pharmacy providers in the future?

The unanimous answer is: Those who can integrate medical and pharmacy data—creating the ability to track and analyze health outcomes—and demonstrate how the various distribution channels serve specific patient needs, will lead the way.
**Question 6**

How do you see the various channels evolving?

<table>
<thead>
<tr>
<th>Distribution Channel</th>
<th>Comments About Evolution</th>
</tr>
</thead>
</table>
| a) Oral               | ▸ More oral medications will be available; more convenience for patients.  
                        | ▸ More focus on which benefit design is better.  
                        | ▸ Dilemma of more patient convenience and responsibility vs. what needs oversight.  
| b) Infusion           | ▸ Potential movement from doctor’s office or hospital setting to outpatient settings.  
                        | ▸ Increased home care options.  
                        | ▸ Prediction by most stakeholders: Physicians will fight to protect revenue associated with infusion.  
| c) Injection          | ▸ Watch infusion evolution for clues to likely changes for injectables.  
                        | ▸ Some possibilities with outpatient and home care access.  
| d) Self-injection     | ▸ More and more patient-centered technology on the way.  
                        | ▸ Some attention to self-injectables at specialty pharmacies whose clinicians can teach patients.  
| e) Adjuvant therapies (such as anti-anemia, anti-nausea agents) | ▸ Not much change expected here—as medical supervision is universally agreed to be necessary.  
                        | ▸ Evolution, if it occurs, will be where medical practices own or have special arrangements with specialty pharmacies who have trained clinicians administering.  
| f) What is the role for retail pharmacy? | ▸ Many stakeholder leaders believe that retail’s new frontier is specialty pharmacy—as long as they equip themselves with the right facilities and staff specially trained in specialty pharmacy patient needs.  
                        | ▸ Some believe retail should stay away completely from specialty pharmacy.  
                        | ▸ Some believe the expected increase in orals is the big opportunity for retail.  
                        | ▸ Some believe retail pharmacy’s new partnerships and joint ventures with home care and infusion centers will help a great deal in some geographic areas.  

Question 7

Do you see the migration of coverage from the medical benefit to the pharmacy benefit continuing? What are the potential gains vs. risks for patients and for the system?

Most of those interviewed for this report believe the migration from medical to pharmacy will continue. They share mixed views on what they think the outcome will be. Many seem to believe the pharmacy benefit data advantages could mean that more patients and care plans will be better managed. Utilization review will be much easier. They voice concern, though, over the likelihood that such changes will mean greater out-of-pocket and co-insurance charges for the patient—which could delay or derail the treatment plan. Cost-related pressures already are known to cause non-compliant behavior, so those concerns are echoed by all. They also believe further migration to the pharmacy benefit could severely reduce essential patient counseling and access to important information—or it could vanish altogether. Finally, those expressing doubts about further migration did so, predicting that physicians who have a great deal of their income in buy-and-bill reimbursement will do what they have to, to protect their revenues from medical benefit procedures. The misalignment of incentives was seen as a growing issue across medicine—and especially in specialty pharmacy matters.

Question 8

How do you see the market reacting to the continuing cost pressure on patient care delivery?

- Increased cost-shifting to patients – to tiers with higher co-pays or co-insurance.
- Less focus on compliance and adherence and more experimentation of pay-for-performance and outcomes-based reimbursement.
- Sacrifices by all and the likelihood of more governmental intervention—especially to permit the entry of bio-similars or follow-on biologics sooner by reducing the amount of time granted for patient exclusivity.
- Greater efforts to tighten benefit designs—with limits on supplies at the point-of-service
- Pressure to implement Comparative Effectiveness Research—with access denials as a result
- Greater attention to cost-benefit analysis and more scrutiny over who accesses high-cost medications and when.
Question 9

What trends and/or barriers do you see in data collection? Please answer for the pharmacy benefit vs. the medical benefit.

The majority of respondents agreed on three central barriers:

1) (Barrier) Matching data from the medical and pharmacy records, so the total medical record and outcome can be seen in a timely fashion;
2) (Barrier) Dealing with the barriers created by HIPAA standards, which are believed to be significant; and
3) (Barrier) Too many channels compounded by too many differing service-level specifics and no standard definitions—everything is customized and almost nothing can be fully compared.

Question 10

What pending public policy changes do you believe will have the greatest impact on specialty pharmacy access and delivery?

The majority of respondents cited one or more of the following:

- Potential actions taken on bio-similars and determining what defines therapeutic equivalency;
- Further development of Comparative Effectiveness Research guidelines and protocols;
- The potential for biomarkers and greater attention to “qualifying patients” for particular treatments;
- The potential multiple impacts of health care reform, including what we’ll do with the doughnut hole in Medicare Part D; and
- The growth of U.S. FDA REMS-labeled products—which will be more task-intensive to manage and may limit distribution even more.
Findings by Stakeholder: Accreditation Groups

Overview of findings
Organizations involved in setting and monitoring quality standards in specialty pharmacy are in very different stages of development. Certain aspects and facets of their work are at very mature stages—with operations that include site reviews in multiple healthcare settings—while other dynamic quality and operations issues aren’t yet fully addressed. All of those interviewed for this report agree that the fragmentation of the U.S. healthcare system—perhaps worst in specialty pharmacy—is due to of the number of healthcare players, suppliers, channels and facilities, complicated benefit designs, and cost challenges.

Basic questions about patient accountability, clinician and healthcare supplier incentives and rewards create layers of complexity that aren’t common in other areas of health care. Simple, clear answers rarely exist, as the field of specialty pharmacy is quite dynamic. The wave of new treatment options in specialty pharmacy requires careful consideration and coordination on a patient-specific basis. Such demands for individualized care that differ by health condition create the impetus for vendor-specific approaches, bound by diverse service-level specifics and performance contracts. In turn, these complexities complicate the everyday practice of medicine. Clinicians and patients, who often share the same goals, have anything but straightforward pathways to treatment.

Expert accreditors agree that the framework for specialty pharmacy changes—so administration and data tracking systems are not adequate. Whether they point to coding issues or other benefit design peculiarities, confusion complicates guideline and monitoring of quality and outcomes. Compliance and adherence rates are impacted dramatically by cost-related issues. Not only are patients unable to afford co-pays or co-insurance, they are stymied by paperwork, access approvals and inadequate or contradictory information they get from their providers. Coordination of the “whole patient’s needs” is often the missing link. A focus on service-level standards is what’s needed—vs. a focus on a given drug.

Specialty pharmacy options will cause greater attention to be focused on personalized medicine. “How we manage those demands, with the rising number of baby-boomers who present with chronic conditions that need true patient-centered care, is the question,” according to one senior executive who believes the amount of self-referrals also will mean an increase in office visits.

How the pipeline of new drug advances and treatment options will be sustained is a big worry among this group. The role of bio-similars and therapeutic equivalency definitions and how the field evolves are of high interest to all.

URAC’s definitions in specialty pharmacy (see Page 14) have been adopted by some—but not all. Common sticking points around service-level specifics are very vendor or business-specific—which creates enormous challenges for payers. Several executives say that a core set of principles and standards must be developed—otherwise, the seemingly random approaches cannot continue. In pediatrics, things are pretty good in centers, with protocols and channel-specific clarity—and things seem to be working. With adults? Not much of

“The standards here must be about the service-level, not about the drug.”
—a leading pharmacy accreditation executive
anything is specific—things can seem almost random. There are all sorts of “work-arounds” and often, they come from inconsistencies across the specialty pharmacy suppliers—or more simply a result of poor communication.

**Key issues and discussion points**

- For Oncology and other complex conditions in particular, companion diagnostics or biomarkers, will allow much greater and more effective patient targeting. Comparative Effectiveness Research will help, too. Accreditation executives believe there will be a much greater trend toward case management in specialty pharmacy.

- Specialty pharmacies will be differentiated by a number of things, including how well they coach and counsel patients, to help drive the outcomes that health plans and others seek. Key to this will be carefully examining quality, dispensing efficiencies, customer service triaging [of patients], and better defining the role for PBMs and case managers to help deal with the increasing amount of confusion that patients have.

- Some believe that either price controls or totally different negotiating practices will help determine more appropriate pricing of specialty drugs and services. Ultimately, managing specialty pharmacy drug pricing and payments according to outcomes (which means compliance and adherence will become more important than ever) is the most important goal.

- Regarding channel evolution, directives for manufacturers to keep the focus on the science is what will drive channel evolution, by medication class and type of delivery mechanism or administration. There are companies that are driving business in one channel or another—to their own gain. In the process, there is further erosion of the value of pharmacists.

- A number of executives believe that there will be a much greater degree of commodization—and with the trend toward much better integrated delivery systems including health IT and electronic medical records, so that much more of what we do will be managed. Comparative Effectiveness Research and the power of better data analysis will bring about real improvements.

- Tensions between drug companies and others over their revenue streams vs. the need to manage costs overall will continue. All agreed that the doughnut hole in Medicare Part D must be addressed. Health reform hopes are high—because many believe mandatory coverage will increase the need for improved standards across medical care, common definitions and high-quality outcomes.
Overview of findings

Cost, affordability, and translating cost into value are the key concerns for employers who are beginning to more proactively address the issues and specifics associated with their specialty pharmacy coverage. Currently, pharmacy benefit managers (PBMs) and benefit consultants, whom many employers depend on to create and monitor their group health, traditional pharmaceutical and specialty pharmacy needs, are prompting this new focus. Employers report relying on the use of traditional pharmacy management tools, e.g., step-care, tiering and cost-shifting. (There is, however, tremendous recognition of and appreciation for the fact that cost-shifting with pricey co-pays in this category of medications imposes a substantial burden on their employees and dependents.) Careful attention to benefit design architecture is seen as an important way of assuring utilization of appropriate resources and compliance with prescribed care plans.

The complexity of the current specialty pharmacy dispensing channels and diverse settings, and their impact on employers/plan sponsors and covered members often is cited as confusing. With that confusion, treatment time lags or delays often are experienced, so that a great deal of manpower and resources are necessary to “understand and work the system” so that patients get what they need. Employer leaders interviewed for this project expressed the need for more timely and up-to-date information about current products and what’s coming in the pipeline (and what it means for them and their plan design) in order to make the best decision for their members and dependents. Finally, there is a clear need for transparent, accessible and actionable information and tools that will help employers track outcomes and better understand what types of approaches work best in which patient populations.

Key issues and discussion points

- Medication cost is a key concern for employers. While still a relatively small percentage of total health care spend, the cost growth of specialty pharmacy is clearly recognized and watched carefully. The perception is that the cost curve has slowed in the past year but employers are wary of this in light of the continuing focus on these types of medications, driven largely by the PBMs and benefits consultants.

- Employers are concerned with the current complexities involved with specialty drugs. This includes definitions of what is covered, distribution channels and the interrelationships between specialty pharmacies and the existing PBMs and health plans. Limited distribution channel access presents benefits and employee relations issues. Employers are looking for better coordination between specialty pharmacy, PBMs and health plans to assure appropriate care management.

- Employers are acutely aware of the out-of-pocket burden associated with the drug benefit; thus, there is little appetite for continued significant or additional cost-shifting to employees. Benefit designs mirror this concern. Several respondents expressed curiosity about how a value-based benefit design might be applied to drive specialty pharmacy utilization and better compliance and adherence. One employer is considering stop-loss coverage as financial protection.
Instead of cost-shifting, there is greater interest in looking to proven pharmacy benefit management tools to help mitigate the trend. While not initially used by plan sponsors in the specialty drug area, the present and perceived future cost pressures make employers far more willing to contemplate and adopt step therapy approaches, utilization review, and medical necessity determinations on a condition-specific basis. However, employers are not as aggressive in adopting these tools for management of oncology medications. The perception is that these patients have special requirements that may not be adequately addressed if care is moved away from the oncology provider.

Employers also are more and more aware that the specialty pharmaceuticals pipeline is growing and additional indications coming from existing drugs are more common. They are intimidated by the pipeline, the additional indications and want better ways of understanding what is on the horizon and what it means for them and their budgeting processes.

The advent of genetic testing/personalized medicine and better patient targeting through biomarkers and companion diagnostics is an area of growing interest by employers. (This is one tool to help determine and measure value.)

Similarly, changing the dispensing/administration site from the physician’s office to other locations is of interest and could prove to be important. Requiring patients to assume more responsibility for care, e.g., managing orals and self-injection also were mentioned. Employers are aware of the potential role of the retail pharmacy in managing cost but are adopting a cautious attitude.

Availability of bio-similars and/or generic formulations of current branded medications are seen as a potential cost management tool. Therefore, employers are watching federal policy and regulatory developments on them as well as related patent law protections.

Employers rely on PBMs and their benefits consultants to better understand coding issues that cloud analysis. They described the current coding and analysis as having a “mystique.”

Employers perceive that those involved with specialty pharmacy as a whole could provide more connectivity with the patient, adding a “human element” to the process. Patient education gaps are enormous.

Employers emphasize the need for integration with care management to be as important as customer service and patient education. Ultimately, finding best practice examples and tracking specific health outcomes on a condition-specific basis are needed.

“Employers want the most or best drug for their money and pharmaceutical companies want the most money for their drugs!”

– a leading human resources executive
Findings by Stakeholder: Employers

Patient Accountability

- Physician Office Visit Occurs
  - Physician Writes Prescription
    - Patient
    - OR
    - Specialty Rx Provides Service
    - Potential for Disease Manager
    - Patient Education & Coaching
    - Plan Sponsor Pays Claim
    - Health Plan Approves Rx
    - Pharmacist Dispenses Rx
    - Patient Accountability Assistance Or Intervention As Needed

Source: JC Consulting Group, Inc. © 2009
### Sample RFP Components: Key Service Elements of a Specialty Pharmacy Vendor

1. Provide published listing of medications to be covered by the specialty pharmacy vendor for inclusion in communications materials.
   - Differentiate between “regular” PBM coverage, specialty pharmacy coverage.

2. Establish and provide information on sub-contracting to alternative or disease-specific specialty vendors for medications not covered as above.

3. Determine individual eligibility for plan coverage at point of claim submission.
   - Link to PBM?
   - Link to Health Plan?
   - Separate eligibility listing from plan administrator?

4. Dedicated patient management call center function.

5. Condition/Disease specific management capability.

6. Establish appropriateness of medication and dosing.
   - Maintain DUR program

7. DUR guidelines.

8. Conformity with prescribing guidelines for the requested medication.
   - Step therapy where appropriate.
   - Confirm appropriateness with genetic testing as applicable.
9. Establish pricing and adjudicate patient claims as per plan design and administer patient billing where appropriate.
   • Co-insurance levels.
   • Imposition of deductibles for select employee/retiree populations.

10. Distribute medication to patient.
    • Retail
    • Mail
    • Special facility

11. Conform with agreed-upon measures of dispensing accuracy, timeliness and financial accuracy.

12. Provide patient and plan sponsor 24/7 access to a licensed pharmacist.

13. Coordinate disease management programs with medical plan.

    • 30-day minimum contact

15. Monitor patient side-effects and report as necessary.

16. Adhere to quality assurance programs established by FDA or other governmental agencies that are specific to the medications being dispensed/managed.

17. Provide 1st level appeal process for any claims denied.
    • 24 hour turnaround.

18. Produce monthly, quarterly and annual management reports and/or claims tapes as requested by plan sponsor.

19. Comply with plan sponsor claims auditing.
    • Comply with SOX auditing guidelines.
Employer Benefits Consultants

Overview of findings

Typically, employers rely on employer benefits consultants (EBCs) to help develop population-specific strategic goals, health education and program objectives, analyze market dynamics and trends, identify the appropriate choice of vendor(s) for specific needs, tailor plan design and evaluate outcomes and trends across the health management continuum. Confusion in one or more of these areas—related specifically to specialty pharmacy—was cited by consultants as growing barriers that are evident today in much of their client work. In particular, the complexities of specialty pharmacy are driven by:

a) the lack of consistent service delivery definitions, i.e., the basic challenge in reviewing responses to RFPs for coverage;

b) multiple distribution or dispensing channels and management thereof, e.g., understanding that a given class of medications may have multiple dispensing or distribution channel options; and how to keep current with which vendors provide which types of services;

c) challenges with data acquisition and analysis;

d) difficulties in gauging and determining the appropriateness of benefit design options; and

e) monitoring and interpreting the pipeline of new therapies.

Each of the aforementioned factors can be quite intimidating to the employer decision-makers and their C-suite colleagues. Generally speaking, employers are seen as being less involved in managing this aspect of their population healthcare planning, as they tend to assume that their pharmacy benefit manager (PBM) will manage specialty pharmacy issues, trends and needs as they arise.

 Consultants believe the future of specialty pharmacy will first be evolved by moving beyond cost competition and becoming more focused on integrated care delivery. In all delivery or dispensing channels, greater energy and resources directed toward outcomes management could and should be extended to an outcomes-based payment model.

Legislation for Comparative Effectiveness Research and the availability of bio-similars (sooner) should help with cost management. Stop-loss coverage or some national uniform “treatment tax or subsidy” may provide an innovative way to limit outlier cost-exposure.

Key issues and discussion points

- Rising costs and affordability are prominent issues consultants hear universally from their employer clients.

- While benefits consultants indicate that employers are aware of present and potential cost growth for specialty pharmacy products and services, current costs for many specialty drug categories are more favorable than what was previously forecast. (This gap helps to generate skepticism when reviewing forecasts and trending information that employers get from their PBMs.) To deal effectively with this issue, many consultants urge their employer clients to have a specialty cost management strategy that focuses on appropriate, evidence-based care.
Consultants often propose developing a strong contracting strategy coupled with clear service-level agreements as a preferred means of managing cost. However, the consultants surveyed for this project report that, in general, clients do not pursue the advice. In most instances, there is no separate focus on specialty pharmacy; instead, there is significant reliance on the PBM of record for such guidance. “There is a concern that clients have nearly ‘blind faith’ in their PBM.”

Benefit design is another major issue. Consultants report that their clients not only wrestle with how to make basic coverage decisions but also the growing out-of-pocket burden for employees. (The issues posed by coverage under the medical plan vs. pharmacy plan are cited as particular barriers.)

Employer clients clearly want to measure costs and outcomes within their various coverage options and plans. The complexities involved on the medical side, with J-codes, which include inadequate reporting and cost-bundling issues are off-putting. This issue, coupled with utilization and cost management advantages on the drug benefit side, drives the ongoing trend to cover more therapies under the pharmacy benefit.

Perceived advantages of migrating coverage from medical to pharmacy ultimately may be offset by three factors:

1) Many clients fail to address the implications of distribution through retail and, thus, diminish the potential impact of the move.
2) The well-known disparity of the out-of-pocket burden for patients that is virtually always higher in the pharmacy benefit vs. in the medical plan will result in unintended consequences and employee relations issues.
3) Lack of appropriate out-of-pocket limits could raise ethical issues. Reader’s Note: There is anecdotal evidence that some employees know how to “game the system,” moving between providers to minimize OOP costs to them. This is almost always at the expense of ongoing care continuity and optimal treatment standards. (Employer clients are aware that this ultimately increases their costs due to incomplete or inadequate treatment—the equivalent of starting over.)

Consultants also reported that oncology drugs, as well as treatments for HIV/AIDS, will not be subject to controls or channel management. Consultants expressed that, often, their clients are simply unwilling to be identified as having created access barriers to specialty medications for these conditions. Similarly, they are discouraged by the seeming lack of progress made in constructing patient-centric approaches for oncology treatment.

Consultants openly and readily identified potential conflict of interest opportunities with specialty providers. The lack of controls associated with appropriateness of medication as well as quantity limits and lack of cost/revenue transparency all are seen as serious and growing issues.

Auto-shipping via the mail service option assures less patient interaction than what would occur in some other channels also is cited as a particular concern.
Overview of findings*

The top issue reported by all four market leader health plans was the high cost of specialty drugs—compounded by the annual cost increases. They perceive that the major cost driver is the pipeline. More products are coming to market at a faster pace and at a higher unit price, so the need to integrate them properly—determining their best use, in which patients and when, is a constant challenge. Plans say they feel they have to manage the “affordability factor” not only for themselves, but for all of their customers and patients. The added burdens spurred by the aging population which presents with a higher incidence of chronic conditions—often with complex co-morbidities—makes the questions about the best fit for these technologies and into what type of benefit design product very difficult.

Plan executives explain that they have to look at each drug, or condition-specific stage for indications, in order to determine what strategy or management controls to use. Implementing those strategies are complicated by the differences among specialty pharmacy providers. They range from high-touch, full-service; highly integrated providers to those who tend only to pick, pack and ship. The complexity of the distribution channels, incomparable service levels and limited distribution drugs also present management challenges to the plans.

To be the most efficient, health plans need to create integrated, full-service networks to support and manage specific health conditions. However, single-source or limited distribution drugs create immediate barriers if they are available only through one pharmacy (and that pharmacy is not in the network). In that situation, when the patient has to go outside the plan network, the intended support mechanisms to help access and receive the drug are not necessarily the same. Since competition is limited, cost and service-level specifics often are impacted. Given current scenarios, plan leaders believe that specialty pharmacy providers that fully integrate with the health plan network and all payers involved and also meet pricing/distribution requirements will be the ones to truly distinguish and differentiate themselves.

Most of the plans report that they continue to experience a wide variety of issues with infusion services done in physician offices or clinics. The combination of keeping current with clinical guidelines, protocols for implementation, reimbursement, buy-and-bill economics, benefit design and lack of real-time data from medical claims complicate efficient management are all factors in the care and management of infusion patients. (Examples of conditions requiring careful management and attention include Oncology, Multiple Sclerosis, and some treatments for Rheumatoid Arthritis are examples.)

* Health Plan respondents include diverse plans such as Aetna, Kaiser Permanente, United Health Group and WellPoint. Similar to the pharmacy benefit manager group, their specialty pharmacy programs were either managed internally, by an owned provider or through contracts with multiple providers.
Key issues and discussion points

- Plan executives predict that there will continue to be some migration from the medical benefit to the pharmacy benefit to improve control and the availability of real-time data. The downside risks inherent to the patient due to the expected increases in their out-of-pocket costs are considerable. One plan indicates that their focus is on creating a better balance between the pharmacy and medical benefits to reduce the financial impact on the patient and the anticipated confusion in the system.

- Cost-shifting to patients will continue. While many of these leaders and others once thought that the availability of bio-similars would reduce annual costs for these therapies, there were concerns expressed over a given plan’s ability to conduct step-therapy or mandate substitutions with new follow-on biologics or bio-similars. Further, estimated annual savings made possible by follow-on options are not as high as what was once predicted.

- Service is paramount, so plans also have to determine the most efficient ways to deliver clinical expertise, positively influence patient care experiences with current information and education that helps impact health outcomes.

- In the buy-and-bill model, plan leaders expressed their reluctance to irritate providers who are critical to their networks by radically altering or removing their buy-and-bill spread revenue.

- The whole idea that there is a special category of drugs called “Specialty Pharmacy” is problematic. Thinking of them separately from all the other drugs that we manage with the health plan has created some unfortunate downstream effects.

“One of the big issues is that Congress has been bamboozled into creating a distinction between drugs and biologics.”
– a leading health plan executive
Overview of findings

The most pressing issues reported by the manufacturer respondents were concerns about patients' access to drugs, services and affordability. Affordability issues were expressed as being problematic for all. They acknowledge that costs challenges are driven by three primary things:

- the cost of bringing products to market;
- price increases; and
- the number of products being introduced.

One executive described that, for payers, the cost of specialty drugs is simply not sustainable—saying the issue is “game-changing.” Some are openly admitting that they are re-evaluating their strategies. With bio-similars on the way, the longer-term view from one executive was that an increase in competition would result in overall improvements in the quality of patient care with some degree of cost reduction.

Manufacturer representatives indicate that more and more plans are reacting to the cost of specialty pharmaceuticals by creating tiers specifically for specialty products that come with higher co-insurance and more intense utilization management. They expressed deep concerns about how such changes already are negatively impacting patient access—as well as the impact on patient’s out-of-pocket responsibilities.

Higher levels of utilization scrutiny and management, differences in the way channels are approached, together with more cost-shifting to patients also can cause inappropriate switching of therapies. Benefit design disparities between intravenous and oral products also are reported to be an issue; manufacturers believe those disparities must be addressed when more oral products become available. While oral products will be much more convenient for patients, they will cost more. Manufacturer leaders interviewed for this report believe they should be managed through specialty pharmacy providers who will focus on compliance, improve outcomes and reduce waste.

These respondents also expressed concerns about the impact of limited distribution drugs. In some situations, patients can’t get the drugs they need because of geographic or socioeconomic conditions. Dealing with such disparities also depends on whether employer purchasers, plan sponsors and health plans demand clear definitions of service. Even though specialty pharmacy providers reduce as many barriers to access and reimbursement as they can—which manufacturers strongly believe helps tremendously—the issues are still there. Manufacturer leaders believe that the role of specialty pharmacy providers is integral to achieving the best possible quality of care and outcomes. Ensuring use of the most effective treatment protocols can increase patient compliance by an average of 10–15 percent over what is seen typically in the retail pharmacy setting. They are continually looking for the best practices and believe that watching the end-stage renal dialysis modeling as a potential best practice could be worthwhile.
Manufacturers seem to be enthusiastic about biomarkers to increase the likelihood of identifying patients with the best potential for treatment success. They worry, though, that costs of biomarkers for new drugs may present an additional cost hurdle. They believe that payers need to see documentation of cost-savings if they are to invest in these combinations.

The breadth, depth and completeness of data are lacking largely because of the gap between pharmacy, medical claims and the lack of patient diagnosis information. Respondents expect health information technology to help with the migration to electronic medical records over the next five years. Along with better bridging of data, those improvements will bring a better understanding of how various discrete patient populations are being managed. There are, however, HIPAA barriers to overcome to enable fully integrated patient data.

On the policy front, most of the respondents we interviewed for this report indicate that bio-similars present a major concern; however, the degree of concern depends on company-specific lines of business. Bio-similars will change the revenue model and what resources will be available for wrap-around services—especially those provided by specialty pharmacies and through patient assistance programs. One individual remarked, “So now, it’s our job to innovate faster, so we don’t have to worry about bio-similars.”

Key issues and discussion points

- The market needs to move beyond compliance and adherence to outcomes management with outcomes-based performance contracting.
- Manufacturers strongly desire alignment of incentives across the market. They perceive “middle men” with administrative service contracts to be steering patients to higher-cost products to improve their own margins. Physician-driven buy-and-bill incentives are another major issue. In one case, physicians were reported to be directing patients to products where they are reimbursed for doing so!
- The evolution of Comparative Effectiveness Research and health care reform are expected to have a huge impact on specialty pharmacy. Manufacturer respondents expressed serious concerns over an expanded governmental role in health care delivery. They continue to support and protect healthcare decisions being made by the patient and the provider.
Overview of findings

Advocates for patients with diverse chronic health conditions that depend on access to specialty drugs are concerned equally with escalating costs, increasing access and affordability issues brought on by more cost-shifting to patients, along with the worsening fragmentation of care coordination and almost-constant educational and support needs.

Almost daily, patients battle the health care system’s maze of paperwork, health plan approval processes and uncertainties about how to obtain their treatments. Keeping up with complex treatment regimens, distribution channel and which benefit covers what—“are enough to make you sick,” according to one group interviewed for this report. “And then you have your health condition and your activities of daily life to contend with. Unless you have been the patient or have cared for someone who has to navigate all of this, you just can’t appreciate just how difficult things are.”

In many cases, out-of-pocket costs for patients are simply impossible to pay. Well-intentioned patient assistance programs sponsored by drug manufacturers don’t always provide relief—because the criteria for access and acceptance requirements are not as easy to meet—so many find program applications to be overwhelming.

Constant changes in benefit design, new knowledge about dosing levels for specific disease stage and development combined with relative inexperience with some new drugs make the road to good health very difficult for patients and their providers. Many who provided their views and perspectives hope that the confusion and many complexities associated with specialty pharmaceutical care will be alleviated by the availability of electronic health records—and improvements in transparency between and among the many providers patients see.

Executives in groups advocating for patients and their families are encouraged by the many new drug options—especially oral medications for cancer and more self-injectables and home-based services that will create greater conveniences and better health outcomes. The future will bring more targeted therapies, which will mean that patients must be qualified—for coverage and specific treatment access. For clinicians, this will mean more paperwork, more information transfer and validation of data. Improvements in compliance and adherence rates are expected.

Keeping clinicians current with all the new advances, channel requirements and restrictions present challenges of a whole different magnitude. Balancing benefit design differences by health plans, network requirements for reimbursement, updating staff with clinical guidelines and tending to individual patients’ needs are contribute to the patient experience. Understanding how healthcare is changing—whether it is how to access new technology entering the system or how to maximize health benefits and covered services—is the bigger, long-term issue, according to patient advocates. Patients essentially look to their physicians for guidance and information and they aren’t involved with or care much about drug pipelines. They hope user-generated information available online will become more and more standard—so that finding credible, real-world information about treatments and their effects is easier.
One leader observes that, “We’re starting to see a blurring between specialty pharmacy and good case management. Care and management of chronic conditions need to be considered in the community setting—not just in the hospital.”

Side effect management, including cross-reactions and drug-drug interactions all require intense patient education across the spectrum of diseases and treatments. Certainly, when a patient is undergoing long chemotherapy treatments, there is an opportunity for nurses and others to use the treatment time to discuss many important aspects of care whereas with orals, the interaction opportunities aren't the same.

For decades, cancer has gotten more attention—and payers rarely block or challenge oncologists’ orders for care and treatment services. Advocates for other conditions contend that patients with many other diseases—such as Rheumatoid Arthritis, Multiple Sclerosis, Cystic Fibrosis or Hemophilia—don’t always get the same kind of attention. There’s a real struggle for attention to certain disease states.

Not all areas of the country have access to adequate, minimum-level resources, which creates a whole set of other treatment barriers. Arranging transportation and support systems to help patients reach comprehensive care centers that have the medical specialists and pharmaceutical care they need is, for some, still a challenge. Quality levels vary, too, so the unevenness of the system shows up in extraordinary ways. One group remarks that their mission is really quite simple: “Helping patients get the care they need is job one.”

Key issues and discussion points

- My organization supports all medication classes and treatment options for all patients—as we believe this is a doctor-clinician-patient decision. Dealing with benefit design issues is always difficult. Population health decision-making is very different than individual health decision-making. Massive educational needs exist. We believe patients’ needs must come first – especially where fear needs to be eliminated.
- We need simplicity for patients. Cost, access and knowing who's in charge of each patient all matter. As the population ages and there are more and more co-morbidities, the best treatments will come from the “village concept” —where the patient, providers and all caregivers are truly on the same page.
- There are privacy barriers, connectivity/interoperability barriers and incentive barriers. There is some awareness of these things and there are attempts to resolve them. The trend toward electronic data and health records will help, as long as it is meaningful and timely. A broader effort on the part of National Quality Forum (NQF) could be helpful.
- Poly-pharmacy problems, dosage changes, and the amount of errors that are possible are top-of-mind and need focus and coordination that specialty pharmacy could facilitate.
- Patients may be taking six to eight medications at once and some of them are off-label. So, while mail-order drugs make economic sense, they should be used only for patients who can demonstrate that they can manage their care and know when to seek medical intervention. This isn't everyone.
- The promise of the medical home concept is exciting: Any willing, capable provider should be able to provide or oversee coordination of these much-needed services.

“This is like a chamber of horrors: Rising premiums, more specialty tiers and higher co-pays! Capping out-of-pocket amounts only means shifting cost. I’m not sure where it’s all going.” — a patient advocacy executive
Findings by Stakeholder: Patient Advocacy Groups

- A greater role for retail pharmacy could be huge; however, with specialized pain treatments where narcotics are concerned, side effects must be understood and monitored by well-trained staff.
- Benefit design complexities are causing providers and patients to play games. We saw similar examples when certain types of care were switched from inpatient to outpatient. Shifts are fine as long as someone is looking out for the needs of patients. We probably need protections or rules. The patient's quality of life must be considered—just as important as effectiveness is what is convenient for patients.
Overview of findings

Professional Medical Societies respondents report their biggest concerns to be access and affordability because specialty pharmacy drugs are totally “out of control” for most payers and patients. Cost and affordability pressures will continue to increase as more drugs are developed and pricing of novel treatments escalates. The sheer volume of products is staggering—especially new treatments for Oncology and Multiple Sclerosis.

Health plans react to these cost pressures by adding complicated tiering systems (Tier 4/Tier 5/Tier 6/Specialty Tier) and treatment complex protocols that require a specialist just to keep track of them. Physicians we interviewed for this report indicate the everyday challenges they face in determining whether a product is under the medical or pharmacy benefit also are issues. Coding has become as difficult as ever for specialty drugs. There is a constant need for clinician education and others in their practices.

One respondent explained, “What we really need is a matrix of all of the specialty pharmacy information for the treating physicians and staff to access during office visits. In many cases, specialty pharmacies just add another organizational layer for the clinician and staff to navigate.”

Frequent changes in benefit design, tier levels and co-insurance also can have a significant impact on the out-of-pocket costs paid by patients, making the access issues even worse. They expressed fear, too, about the migration of some clinical services moving away from the medical to the pharmacy channels—which they believe can result in less-than-optimal side-effect or other quality of life issues management. In the worst-case scenario, care may not be provided at the time of greatest need.

The introduction of small-molecule immune-modulators delivered orally to replace large-molecule biologics requiring injection or infusion were viewed as some of the “most significant advances in medicine.” Novel oral delivery mechanisms for large molecules may very well reduce needs for injection and infusion services and are expected to dramatically improve patient care and outcomes.

Key issues and discussion points

- Professional medical society respondents believe that continuing cost pressures will require intervention of some sort—if not significant reform. Government-negotiated price controls could hurt scientific innovation.
- Getting the “best possible care” means that patients and payers will have to continue to contribute, but how do we determine when we have “stepped over the line”?
- Drug company marketing costs need more scrutiny. “If the money that now goes into marketing and advertising could be put to use in developing better patient educational materials, then the unit price of drugs could be lowered.”
- We need to do a much better job of tracking and monitoring drugs’ effects and what the patient outcomes are. More money for grants for registries and tracking information from clinical trials would be put to good use.
Overview of findings*

All Specialty Pharmacy Provider (SPP) and Pharmacy Benefit Manager (PBMs) respondents identified a number of key issues; which, when combined, easily translate to one of the largest challenges facing the health care industry today:

1) The cost of the specialty medications and its growth trajectory of 17–20 percent per year;
2) The associated costs of administering these drugs and the effect on total drug spend; and
3) The breadth and depth of the pipeline of new specialty drugs (with new oncologic agents in particular and a few therapeutic categories in particular).

Executives representing market-leading organizations interviewed for this project predict that the avalanche of new treatment options coming in the pipeline simply cannot be managed via traditional managed care tactics, formulary design controls or other familiar approaches. New strategies must be developed. One statistic demonstrating this point estimates that the cost impact of these drugs is in excess of 25 percent of the total drug budget, yet only utilized by 1–3 percent of the total patient population.

They also expressed concerns overall about the affordability and coverage of these drugs and how serious issues affecting access, reimbursement, co-pay structure of current benefit designs will be addressed. As specialty drugs grow to account for a greater percentage of the total healthcare dollar, the market is moving toward creating special tiers, adding more co-insurance products and formulary controls for specialty drugs. In addition, access to drugs dictated by manufacturers that restrict or limit the number of specialty pharmacy providers (requiring patients to go outside their network to obtain their medicines and related services) was described as a growing concern and obstacle in certain regions of the U.S. in particular.

Specialty pharmacy providers indicated that margin erosion is having a negative impact on the amount and depth of “high touch” services that they can provide for patients with complicated diseases. Support programs and guidelines are now being developed and marketed on a condition- or drug-specific basis. The U.S. FDA’s Risk Evaluation and Mitigation Strategies (REMS) classification for some specialty drugs is being applied to more and more medications, making the need for accurate dispensing and utilization data and documentation by manufacturers essential for compliance and marketability.

Many respondents said that real differentiation among specialty providers will occur when they demonstrate their ability to provide highly-customized approaches to integrating data and documenting measurable patient outcomes. Currently, these tasks are complicated by delays in matching pharmacy and medical data as well as the lack of uniform reporting standards.

They also contend that cost management strategies will only be achieved if links between appropriate utilization and minimum-level or better clinical outcomes occur. And, since there is no universally accepted definition of specialty pharmacy — nor is there a consistent set of service components associated with specialty pharmacy care and patient management — direct comparisons and outcomes analysis are virtually impossible. One PBM leader sends a professional staff member to visit each specialty pharmacy to do service audits on a quarterly basis.

* Pharmacy Benefit Manager/Specialty Pharmacy Provider respondents include diverse group of organizations with business models that range from an independent specialty pharmacy provider and an independent PBM (that contracts for all specialty pharmacy services) to fully integrated retail/PBM/specialty pharmacy providers. This group of stakeholders has been aggregated because each organization provides a full range of specialty pharmacy services or closely manages those who provide those services for their clients.

“We don’t treat a benefit design, we treat a patient.”  
— a leading pharmacy benefit manager executive
Evolution of the various delivery channels is expected when more oral and self-injectable drugs come to market. And, if chain pharmacies set up specific capabilities and services for patients taking specialty drugs, a shift in market dynamics is expected to occur. Interviewees predict that if retail pharmacy companies invest time, resources and focus well on what they can do in their stores or special clinics, they could play an important role in the growing needs in specialty pharmacy. All agreed that they would need to have a proper space with a specialist, trained in the special needs of these patients. Teaching and counseling patients on how the medications work, what side effects must be watched carefully, and when self-injectables may be appropriate options to help save on costs are the keys to a successful retail-based operation.

All of those interviewed said they believe that bio-similars will have a positive impact on affordability and access issues—but not as great as what has been experienced in small molecule generics. Estimates of savings that are expected to come from the availability of bio-similars range from 20 to 30 percent of what the branded products now cost. As more and more products become available, interviewees for this project say they will prepare substitution strategies—but the specifics regarding what constitutes therapeutic equivalency must come first from the U.S. FDA.

Key issues and discussion points

- Reimbursement and profitability will continue to be an issue for specialty pharmacy. This is not limited to maximizing reimbursement for the drug, but also for reimbursement of the complex and patient-specific needs and services deemed to be essential components of their care. To further complicate the care management continuum, there are accepted clinical rationale for managing specialty drugs under the medical benefit vs. the pharmacy benefit.
- PBMs are currently working hard to “crosswalk” or tie coding from the medical and pharmacy data so that benefits management is easier for their clients.
- Some of those surveyed expressed serious concerns that, as a result of the cost of the medications, market growth and annual price increases, the marketplace has become extremely price-sensitive. Some plan sponsors have elected to have products dispensed—without the array of supporting specialty services or monitoring of progress or outcomes. The impact of this trend could be devastating to patients and would surely drive up costs for plan sponsors over the longer-term.
- The concern about the escalating out-of-pocket burden on patients was expressed by all. With the shift from the medical to the pharmacy benefit, there can be significant co-pay swings for the patients, along with related reimbursement and pricing implications.
- The lack of definitions for specialty drugs compounded by the lack of uniformity in how services are defined and provided by providers, plans, physicians, or PBMs, is a growing challenge. The level of services offered and the data capability differences complicate the contracting and evaluation processes.
- Oncologic agents are expected to remain in the medical benefit and be administered in the physician’s office, according to the market leaders who participated in the FMCP project interviews. Anti-cancer therapies have been treated as or considered to be unique because often, they are deemed to be potentially toxic agents that require constant monitoring and dosage needs are considered carefully at every patient appointment. In essence, the medical specialist becomes the “primary care” physician for the patient.
Findings by Stakeholder: Specialty Pharmacy Providers & Pharmacy Benefit Managers

- Many plan sponsors are moving toward not covering self-injectable products under the medical benefit (insisting on covering only under the drug benefit) while still others want to create or expand Preferred Drug Lists (PDLs) and would like to eliminate the buy-and-bill model completely. Growing concern was expressed over the negative impact that benefit changes would have on patients.

- Manufacturer contracting in specialty pharmacy is another trend that was reported. With more products available, there is an opportunity for plans and sponsors to strengthen formularies, creating specialty PDLs that create an advantage for one or two products. With the growth trend in these products, price guarantees are as important as rebates with those contracts.

- From a policy standpoint, PBM leaders expressed collective hopes that bio-similars would be available soon and that Comparative Effectiveness Research holds the greatest potential for comparing future therapies with those already available. In addition, greater demands for and use of electronic prescribing by physicians would change the dynamics of benefit management, compliance and adherence—and ultimately, better health outcomes information.

- As the costs of the drugs rise, margins are eroding. Fewer employers/plan sponsors support the critical management of complex disease states and related patient needs. Since specialty pharmacy includes a matrix of drug delivery and support which are drug- and condition-specific, the current lack of appreciation for that matrix is a growing concern among providers. And, without specific reimbursement for the care management continuum, financial concerns abound.

- Specialty pharmacy providers can differentiate themselves is they capture and analyze data in a way that helps purchasers to evaluate outcomes.

- In order for specialty pharmacy providers to fully perform and achieve the best possible patient outcomes, they need access to the complete medical record information. This will allow them to consider the overall care program and intervene in an informed way. Focusing on administering the drug only is problematic for all concerned.

“If you’re infusing a drug that costs the patient $18–20,000 per month, higher expectations about outcomes should be expected.”

– a leading pharmacy benefit manager executive
To anchor and validate findings from our Primary Research, JCCG undertook a comprehensive review of publicly-available information with the help of Shanahan Capital Ventures, LLC and Jonathan Chenoweth and Carly Fuhrman, students at the University of Washington School of Pharmacy, working at the direction of faculty advisor Peter M. Penna, PharmD. The timeline for this research was July through October of 2009. All items, procured for this part of our work, are available on the CD-ROM containing an index with over 300 entries and is attached to the inside back cover of this report.

**Sources**

JCCG’s Work Plan components covered in Secondary Research include:

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<td>Books, book chapters, white papers, publications and brochures</td>
</tr>
<tr>
<td>Key accreditation groups, policymakers, U.S. government agencies, and other key pharmacy groups and influencers</td>
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<tr>
<td>Peer-reviewed health, medical and pharmacy journals and key health business publications read by payers</td>
</tr>
<tr>
<td>Payers including employers, health plans, government, specialty pharmacy providers, pharmacy benefit managers, manufacturers—including makers of specialty and biotechnology products</td>
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<tr>
<td>Professional medical societies and associations</td>
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<tr>
<td>Service-level specifics and delivery models in specialty pharmacy</td>
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<tr>
<td>Technology assessment by leading groups/review of specialty drugs by disease category</td>
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<tr>
<td>Impact of follow-on biologics, bio-similars review by U.S. Food and Drug Administration and definitions of therapeutic equivalency</td>
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<tr>
<td>Companion diagnostics</td>
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<tr>
<td>Legislative/political/policy climate—with a focus on pending Federal, state and legislation</td>
</tr>
<tr>
<td>Patient Advocacy Groups focused on health conditions dependent upon access to specialty pharmacy drugs and therapeutics.</td>
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Summary of Research Highlights

The first step in our secondary research was to search for and compile documents by key word and other classic search modalities to reveal definitions and terms used in the literature and other available publications that pertain to specialty pharmacy. Pharmacy organization websites and specialty pharmacy websites were the best source of information for addressing definitions. In a few cases, national organizations post their own statements about specialty pharmacy.

Typically, the Private Sector describes specialty pharmaceuticals as high-cost injectables and oral chemotherapy drugs (ranging from $10,000 to $300,000 or more per year), that treat complex, chronic diseases, and require special handling, packaging, storing, patient education and monitoring. By contrast, Medicare’s definition cites a lesser annual cost minimum of $600 or more per month or $7,200 or more per year.

Specialty pharmacies manage all aspects of administration, essential care management services and other condition-specific patient care needs associated with specialty drugs.
and therapeutics. On the accompanying CD-ROM, 95 documents provide information about company-specific partial definitions or descriptions of service-level specifics and any other relevant items included in patient care management. Inconsistencies across those 95 examples are evident in virtually every source example—whether in basic definitions, descriptions of scope and type of services, distribution channels, those focusing only on certain health conditions or particular offerings, or other facets of product offerings.

Regarding benefit design, our research database includes 151 documents relating to benefit products, covered services with deductibles or co-insurance, plus formulary management strategies associated with service-level specifics in specialty pharmacy. The most complete source for this information came from health plan websites. As expected, many have a fourth tier, or specialty tier, with a 25–33 percent co-insurance vs. the more traditional co-pays. Co-insurance products pass more coverage responsibility to patients, which usually means a higher proportion of the drug charge comes back to them.

Health plans also manage high-cost specialty pharmaceuticals by limiting amounts dispensed to a maximum of 30 days’ supply at each point-of-service in order to ensure that the expected progress is occurring and to prevent waste. Some mandate that all subsequent refills must be done through designated specialty pharmacies. While health plans are continuing to develop strategies to manage high-cost specialty pharmaceuticals, strategies differ from plan to plan. In addition, we encountered quite a few websites whose specific benefit designs for specialty pharmacy products are secured. Unless you are a provider or patient associated with that particular health plan, details are not available.

For service-level specifics, websites of specialty pharmacy providers were the most useful and complete information sources. The most heavily-advertised services provided by specialty pharmacy providers include:

- Convenience of care delivery
- Case management
- Patient education, including refill reminders
- Coordination of care components, including benefit management and 24/7 customer support

The majority of the specialty pharmacy providers we examined offer most or all of these services. Some offer additional services such as reporting and outcomes research data for their health plan, employer, plan sponsor customers or others. Many also advertise their ability to purchase and deliver limited-distribution drugs that might otherwise not be available. Specialty pharmacies claim they provide a wide variety of services focused on optimizing patient outcomes.

All of the specialty providers’ websites have sections for payers who want to explore the advantages their particular pharmacy management services. They consistently advertise their services with many similar items, such as 24-hour pharmacist availability, refill management, reporting and other unspecified techniques to help payers manage costs.
Information about business relationships among the various providers is not readily available or is disclosed rarely on company sites. Market dynamics, contract details and relationships between and among companies, including merger and acquisition activities, all contribute to the lack of business relationships or ventures. Keeping current with quarterly analyst reports and or other company news postings is often the only way to know these relationships. Specialty pharmacy providers’ associations with PBMs were somewhat easier to identify—in governance, business unit or other section describing partnerships. Our database includes 114 documents dealing with these relationships.

Our database includes 34 documents about the pipeline of specialty pharmacy. Listings are located in a wide variety of government and private sector sites, including the one provided by the Pharmaceutical Research and Manufacturers of America (PhRMA) report that shows a total of 633 biotechnology drugs currently in clinical trials. PhRMA reports approximately 37 percent (254 different drugs) are for oncology. Oral chemotherapy agents make up 35 percent of the oncology pipeline. Next in volume are 162 drugs for infectious diseases and another 59 for autoimmune disorders.

**Peer-reviewed Article Topics**

The articles index shows a variety of topics and themes. The most common ones deal with benefit design, contracting, disease-specific care, and pipeline development. Some articles address the challenges of medical benefit vs. pharmacy benefit while describing what is needed in the design of a sound specialty pharmacy benefit. Reporting and patient access issues often are cited, with more and more research and commentary on out-of-pocket costs for patients—particularly in view of the rising costs of specialty medications. Some also are writing about the opportunities and challenges of developing a sound benefit design in a well-managed home injection or infusion program.

Specialty pharmacy contracting also is discussed. Many of those articles and screenshots dealing with contracting also address benefit design. Many of them focus on the reporting and specifics that health plans or PBMs should expect from specialty pharmacy providers, as well as what employers and plan sponsors should expect from the PBMs who are coordinating subcontractors or directly providing specialty pharmacy services.

Disease management and patient care programs written for provider education also are common. Since many patients have complex health conditions that require specialty pharmacy medications, continuing education is very important to maintain or update clinical knowledge and best practices.

Some articles mention the pipeline—including information and commentary about the potential for biogenerics/bio-similars/follow-on biologics. Regardless of publishing dates of one year to four years ago, they all address the same challenges, offering the same commentary about benefits and results.
Screenshots

Finally, our index contains a number of screenshots from a variety of specialty pharmacies. Home pages show specific sections for patients where they may log in and manage their prescriptions; for prescribers to send new prescriptions and locate resources; for payers who can learn about specific services, programs and contracting methods; and for manufacturers. Larger specialty pharmacies consistently provide information for manufacturers about the specialty pharmacy providers’ capabilities and skills required to bring a new product to market, as well as other services they might provide in partnership, such as reporting.

Sample Publications

BMS Monitor & Survey

Published by: Bristol-Myers Squibb Company
Year published: 2008, updated annually
Primary Audiences Served: General
Advisory or Editorial Board? Yes, including small roundtable group.

Primer on Specialty Pharmacy

Published by: Pharmacy Benefit Management Institute
Year published: 2009
Primary Audiences Served: PBM, Employers and Plan Sponsors
Advisory or Editorial Board? None listed
Secondary Research

AIS Book on Specialty Pharmacy
Published by: Atlantic Information Services, Inc.
Primary Audiences Served: General
Advisory or Editorial Board? None credited

Walgreens Specialty Pharmacy—Outlook & State of the Industry
Published by: Walgreen Co.
Year published: 2009
Primary Audiences Served: General
Advisory or Editorial Board? Internal sources listed

Issue Brief
Published by: National Business Group on Health
Year published: August 2009
Primary Audiences Served: Primarily Large or Jumbo Employers
Advisory or Editorial Board? Members of NBGH Committees
Medicare & Specialty Medications

Today, more than 26 million Medicare beneficiaries are enrolled in Medicare Prescription Drug Plans, including 17.5 million in stand-alone plans and nine million in Medicare Advantage drug plans. Management of specialty pharmaceuticals is critically important to Medicare. While some reports estimate that fewer than 5 percent of commercial-aged patients take specialty pharmaceutical medications, the percentage covered by Medicare is significantly higher—since older patients suffer with more chronic conditions.

Medicare covers specialty drugs and therapies in two parts: in Part B and in Part D (the plan covering outpatient drugs went into effect in 2006). Payment for Part B drugs is administered by local insurance carriers that cover 80 percent of the cost of the drugs and services; while patients, or their supplemental insurers, pay 20 percent.

Part B covers the following categories and specific specialty medications:

1) Injectables and infusions when administered incident to a physician's service;
2) Oral cancer drugs that replace injectables;
3) Erythropoietin for renal dialysis patients with anemia;
4) Pneumococcal and influenza vaccines and hepatitis vaccine in high risk patients;
5) Drugs requiring administration with medical equipment; and
6) Immunosuppressant drugs for post transplant patients.

When Medicare Part D was created, additional specialty medications such as self-administered injectables, certain oral chemotherapy agents, and vaccines (not previously covered under Part B) were included. Drugs can be covered in Part B, Part D (or both) depending on the setting, patient diagnosis, timing of treatment, and the associated use of durable medical equipment.

Medicare’s definition of specialty drugs under Part D is defined as any drug for which the negotiated price is $600 per month or more. Any drug fitting this definition may be placed on a specialty tier, requiring higher patient cost-sharing by the 47 national carriers. National carriers have the option of placing high-cost drugs in a standard or specialty tier. Most of the Medicare national prescription drug plans have a specialty tier and more plans also are opting to charge higher co-insurance for drugs in that tier. In 2009, more than half of all Part D enrollees in plans with a specialty tier were subject to 33 percent co-insurance for specialty drugs.
Part D has expanded access to specialty medications, but cost-sharing is considerable:

<table>
<thead>
<tr>
<th>Medicare Part D Deductibles (as of 2010)</th>
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<tbody>
<tr>
<td><strong>Standard Part D Deductible:</strong></td>
</tr>
<tr>
<td>$310.00</td>
</tr>
<tr>
<td><strong>25 percent of costs:</strong></td>
</tr>
<tr>
<td>when charges range from $310.00 to $2,830.00</td>
</tr>
<tr>
<td><strong>100 percent of costs:</strong></td>
</tr>
<tr>
<td>when charges range from $2,830.00 to $6,440.00</td>
</tr>
<tr>
<td><strong>5 percent of costs:</strong></td>
</tr>
<tr>
<td>when charges go over $6,440.00 (catastrophic coverage)</td>
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</table>

While specialty drug coverage follows U.S. FDA-approved indications, Medicare has no formal criteria for determining the appropriate off-label use other than through the Centers for Medicare and Medicaid Services (CMS) Compendia. (The Compendia is a list of FDA-approved drugs and biologicals or a comprehensive listing of a specific subset of drugs or biologicals in a specialty compendium. Off-label uses of FDA-approved drugs can be added to the compendia.) Since experts estimate that over 50 percent of cancer treatments are administered via off-label use, this allows physicians to have significant freedom. Local Medicare carriers often decide on a case-by-case basis, with off-label use for cancer drugs guided by recognized national clinical treatment guidelines and the CMS Compendia.

Major challenges exist. A great deal of coverage criteria lack standards and quality guidelines that are necessary to make decisions. In addition, since CMS does not consider cost-effectiveness in its coverage decisions, there are limits to how useful economic analyses can be.

At the time of this report’s production, potential changes to the Medicare program arising from national healthcare reform are unknown. Medicare coverage decisions are, by law, based on a service being “reasonable and necessary,” and do not consider cost. In most cases, coverage decisions for specialty drugs, (determining what is reasonable and necessary), are made at the local level by the individual carriers, with national guidance only from the Medicare Coverage Advisory Committee.
Phase I Discovery & U.S. Environmental Scan: Secondary Research

The enclosed CD-ROM contains over 300 documents which were compiled for use with the FMCP Specialty Pharmacy Initiative. Information was collected from July through October 2009 and organized with an Index shown in a Microsoft Excel® file by Document Title, Category, File Name, Year Published, Where Published and Key Words. Index columns can be sorted using the standard Microsoft Excel® “Sort” function. Documents included in this index can be accessed by using the “hyperlink” function that is, in most cases, built into the Document Titles. Websites can be accessed using the same hyperlink. The default is an alphabetical sort by Title.

Hyperlink Function: To access a document shown on the Index, simply “left mouse click” on the Title of the document and the document will be accessed automatically. If the Index lists a website, that website also should be accessed in the same manner. NOTE: FMCP does not track or update hyperlinks or specific access changes that are typical and proprietary to the source.

Categories: All documents have been categorized as follows:

- Abstracts
- News Articles
- Screenshots
- Brochures
- Publications
- Supplemental Publications
- Index
- Policy Briefs
- Web-based
- Links
- Reports
- White Papers

Questions? Contact Michael B. McIntosh, JCCG senior consultant, at (303) 674-2166 or mike.mcintosh@jcconsultinggroup.com.