Specialty Pharmacy Networks for Hospitals in the Offing

Absence of Onsite Access to Specialty Pharmaceuticals Has Care and Financial Implications

Stephen Barlas

Two competing hospital networks are racing against one another to assemble specialty pharmacy programs. Excelera Corp. and UHC, the academic medical center consortium, would serve as middlemen between hospitals and drug manufacturers, supplying the kinds of administrative support, data aggregation services, and clinical follow-up, among other things, that specialty drug manufacturers require in order to deliver expensive, restricted distribution (also referred to as “limited distribution”) drugs to hospitals. Currently, many specialty drug manufacturers decline to provide new, expensive oncology, multiple sclerosis, rheumatoid arthritis, and hepatitis C drugs and drugs in a few other categories to hospitals. These are almost all self-administered oral and injected medications, half covered by the patient’s pharmacy benefit, the other half by his or her medical benefit.

Lack of access is mostly an issue for outpatient hospital pharmacies, but inpatient pharmacies are affected, too, though to a lesser extent. The inability to dispense specialty drugs from their own facilities disadvantages hospitals in several ways, particularly by impeding patient care when hospitals lose access to important information (e.g., about adverse drug reactions, prescription refills, etc.). It also reduces potential hospital revenue.

Health plans are often just as responsible as manufacturers for denial of specialty drugs to hospital pharmacies. The giant health plans such as UnitedHealthcare have their own specialty pharmacies, in this case OptumRx. That is often the only place a hospital clinic patient can fill a specialty prescription. Smaller health plans specify particular retail locations for each drug, those often being pharmacies owned by Walgreens, CVS Caremark, Accredo, Diplomat, or Curascript. All those pharmacies are accredited by either the Utilization Review Accreditation Commission (URAC) or the Accreditation Commission for Health Care (ACHC), sometimes both. For example, the Washington state/Idaho insurer Group Health lists about 40 limited distribution drugs on its formulary. Diplomat Specialty Pharmacy dominates the provider list, with CVS Caremark a distant second.

Prime Therapeutics Specialty Pharmacy was established by Blue Cross Blue Shield plans. It is accredited by URAC, ACHC, and the National Association of Boards of Pharmacy. It has access to 50 limited distribution drugs, states Kelly Sheehan, a spokeswoman for Prime. To qualify to distribute each drug, Prime must meet rigorous criteria including but not limited to: benefit investigation services, prior authorization support, shipment tracking, care management services provided by nurses and pharmacists, and ability to access financial support options for patients.

Some Newer, High-Cost Specialty Drugs Hard to Obtain

Tony Zappa, Vice President, Wellpartner, Inc., which supplies specialty drugs directly to patients (via home delivery) of 340B hospitals, says those criteria are hard for most hospital outpatient pharmacies to meet. “Most outpatient clinics are not staffed to do that, nor do they have pharmacists trained to support uncommon conditions or therapies,” he says.

“Access is difficult because hospital-based specialty pharmacies are a relatively new concept in the eyes of manufacturers, even though many of us have been actively working in this space for 10-plus years,” says Andy Pulvermacher, PharmD, Specialty Services Supervisor, University of Wisconsin Hospitals and Clinics. “For established products with limited distribution channels, it’s difficult to gain access despite the validity of your value proposition. From a quality standpoint, no other pharmacy offers the quality that can be provided by a hospital-based pharmacy with access to the electronic medical record.”

Pulvermacher adds that some categories have historically been restricted. Pulmonary arterial hypertension and hereditary angioedema are probably the best examples. “We’ve seen some restrictions within oncology for non-NCI-designated sites, and a small amount of restriction within the multiple sclerosis space,” he says. “Otherwise orphan and ultra-orphan products will continue to be an issue simply because of population size.”

One hospital pharmacist says some manufacturers are cutting distribution further. He cites the examples of MedImmune’s Synagis (palivizumab) and Celgene’s Revlimid (lenalidomide). “MedImmune has actually ratcheted down its network over the past few years in order to better control inventory and clinical care,” he reports.

Melissa Garcia, a spokeswoman for MedImmune, responds, “MedImmune strives to optimize patient access to our medicines, and continues to review the company’s Synagis Distribution Network to make sure it provides high levels of customer service to all Synagis patients.”

One assistant director of specialty pharmacy services for an ambulatory care pharmacy department at a major academic medical center, who did not want to be identified, cites the drug Tecfidera (dimethyl fumarate), manufactured by Biogen Idec. Tecfidera was approved by the U.S. Food and Drug Administration (FDA) in 2013 as a first-line therapy for adults with relapsing forms of multiple sclerosis (MS). When a patient comes to one of her hospital’s clinics and receives a prescrip-

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tion for Tecfidera, her hospital's pharmacy cannot dispense the drug because of Biogen Idec's restricted distribution policy.

Monique da Silva, a spokeswoman for Biogen Idec, says Tecfidera is currently available through a specialty pharmacy network made up of pharmacies that specialize in MS care for patients. "Due to increased demand for Tecfidera and requests from additional pharmacies to have access to the product, Biogen Idec has created an Alternate Care Pharmacy Network program, which expands the network to the hospital outpatient pharmacy class of trade," she adds. "Any pharmacy requesting access to Tecfidera will be evaluated on a case-by-case basis to determine if they meet the criteria to participate in the Tecfidera network." She declines to provide the criteria Biogen uses or the number of hospital outpatient clinics accepted into the Tecfidera networks.

Rise of ACOs Affects Hospital Dispensing of Specialty Drugs

Being left out in the cold with regard to many specialty drugs has had a chilling effect on hospitals as they have faced the ascent of accountable care organizations (ACOs). On December 23, the Centers for Medicare and Medicaid Services (CMS) announced the establishment of 122 new Medicare ACOs, increasing the ACO total to 360 serving 5.3 million Americans. It is important for hospitals in ACOs to control global costs for individual patients. It is hard to do that if a patient gets a prescription for an expensive specialty drug from a physician at a hospital clinic, but then has to go elsewhere to fill that prescription. "Limited distribution is not a mechanism that will do well in an ACO and capitation environment because hospitals will be responsible for the full cost of care for these patients, including drug products at some point in the near future," explains Pulvermacher.

"We become blinded to information," adds Kyle Skiermont, PharmD, Director of Specialty Pharmacy Operations, Fairview Pharmacy Services. "So we have no information about which pharmacy dispensed the drug, when they dispensed it, when it arrived at the patient's residence, clinical information, or whether adverse events were reported in a timely manner." Fairview Health Services owns eight medical centers in Minnesota.

Revenue Loss an Issue, Too

Nor do hospitals like to see their potential profits lost to Walgreens or CVS Caremark specialty pharmacies. "The seven academic medical centers in the Excelera network have money on their mind," notes Adam Fein, PhD, a principal at Pembroke Consulting, Inc. "Excelera's website states that the hospitals want to stop the 'leakage' of patients to for-profit specialty pharmacy companies. These medical centers are also hoping to acquire specialty drugs under the unregulated 340B drug discount program, so the profits would be very high." The 340B program allows hospitals with high Medicaid populations to buy pharmaceuticals at large discounts and then bill the patient's insurance company for the higher, non-discounted amount, keeping the difference as a profit.

According to IMS Health, estimated costs for specialty pharmaceutical agents were to exceed $160 billion by the end of 2013. The 2012–2013 Economic Report on the Retail, Mail, and Specialty Pharmacies published by Pembroke Consulting, Inc. and the Drug Channels Institute estimates that by 2016, eight of the top 10 best-selling drugs, by revenue, will be specialty pharmaceuticals and that these drugs will account for 31% of the United States’ pharmacy industry revenues.

The FDA forces some manufacturers to limited distribution to specialty pharmacies as the price of their approval. These limited distribution plans are included in the manufacturer's Risk Evaluation and Mitigation Strategy (REMS). The FDA often requires limited distribution when a new drug appears to have substantial benefits compared to existing drugs in the class, but also has unanswered patient adverse effect and safety questions that might otherwise prevent approval, if not for the drug's potential significant benefits. The FDA requires a REMS for about 70 drugs. In six of those cases the REMS covers an entire class of drugs. This is called a "shared" REMS.

To obtain some of these drugs, hospitals have to jump through hoops that might as well be flaming. Even though a hospital inpatient or outpatient pharmacy can theoretically get access to Amgen's Epogen/Procrit (Epoetin alfa), the hospital must be certified through site level enrollment in the ESA APPRISE Oncology Program. That program is run by Amgen, Inc. and Janssen Products, LP; the distributors of Epogen and Procrit, respectively. Enrollment in that program means the pharmacy director must complete the ESA APPRISE Oncology Program Training Module for Hospital Designees, agree to assume the authority and responsibility to internally coordinate and oversee the ESA APPRISE Oncology Program requirements in his or her hospital, make sure the provider who prescribed EpoGEN/Procrit for patients with cancer has enrolled in the ESA APPRISE Oncology Program, and make sure the physician talked about the risks of the drug with the patient and documented that conversation.

Those and other tough conditions can be hard for a hospital pharmacy to meet. A study by the Pharmaceutical Care Management Association released in December backs that up. North Star Opinion Research conducted a national survey of 500 physicians in the rheumatology, nephrology, infectious disease, oncology, and neurology specialties who prescribe specialty medications. Thirty percent say their patients typically get their specialty medications from a specialty pharmacy, compared to 21% from a drugstore, 10% from a doctor's office or practice, 8% from an outpatient clinic, and 6% from a mail-order pharmacy, with 22% saying patients get their medications from a combination of sources.

Typically, the inability to get access to specialty pharmaceuticals is a problem only for outpatient clinics, since these drugs are mostly infused or taken orally by the patient at home. It becomes a problem for the inpatient pharmacy when, for example, an MS or oncology patient is admitted and has either forgotten or run out of his or her specialty drug.

In some instances, the specialty drug prescription written by the hospital outpatient pharmacy can take a circuitous, cross-country path that makes it even harder for the hospital to track. Doug Smith, PharmD, Senior Director, Supply Chain Services, UHC, the academic hospital consortium, describes a hypothetical instance in which a patient visits a Fairview Health Services hematology clinic and gets a prescription for a specialty drug. The clinic or the health plan sends the prescription to a third-party hub, perhaps one run by Lash
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Group, an AmeriSource Bergen company. Lash then passes the prescription to its affiliated distribution arm, TheraCom, which has specialty capability. The prescription is filled for dispensing by a specialty pharmacy in North Carolina, which mails the drug to the patient, who happens to live in Wisconsin close to the Minnesota line—which is why he or she went to a Fairview facility in the first place.

The Rise of Competing Hospital Specialty Pharmacy Networks

By participating in Excelera, which Fairview announced it was doing last December, Fairview hopes to be able to dispense more specialty medications within its four walls and thereby keep closer track of the clinical status of patients, with emphasis on medication adherence. Excelera and UHC will serve as, in one sense, accreditors of hospital pharmacy departments, ensuring they keep training, quality control, patient follow-up, and other standards. They will also allow drug manufacturers to deal with one entity for data input instead of individual hospitals. Doug Smith is one of the UHC staffers working on the launch of that network. He hopes to have it up and running by the end of the first quarter of 2014 with 20 UHC members participating. Excelera and UHC will have to provide 14 core services, including having clinically trained pharmacists working in specialty clinics.

Excelera had been limping along since it was formed in 2012, trying to generate momentum but having difficulty doing so with only five members: Henry Ford Health System, Marshfield Clinic, Avera Health, Fairview Health Services, and Regional Health. But Excelera made a big move in December by announcing its recruitment of major hospital pharmacies Catholic Health Initiatives (CHI) and Intermountain Healthcare. Fairview increased its investment. “We are close to signing our first deal with a pharmaceutical company and are trying to gain members who can meet specific pharmacy standards,” reports Skiermont, who has been involved in Excelera’s operations.

Interestingly, Excelera and UHC would serve some of the same hospitals. Fairview’s University of Minnesota academic medical center is a member of UHC, for example. But some Excelera members are not part of UHC. Smith hopes to have 20 of UHC’s academic health centers signed up for its specialty pharmacy LLP by the end of the first quarter of 2014. Those hospitals will have to meet 14 core service requirements, including having clinically trained pharmacists working in specialty clinics.

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Accreditors Compete for Hospital Business, Too

The importance to hospitals of getting access to those drugs is underlined by the parallel development of Excelera and the UHC network. Hospitals that today have access to some specialty pharmaceuticals probably have a “specialty pharmacy” accreditation, from the Utilization Review Accreditation Commission (URAC), the Accreditation Commission for Health Care (ACHC) or in some instances The Joint Commission, which accredits only hospitals and departments. But ACHC and URAC are the two major players in the specialty pharmacy accreditation game at the moment. ACHC has been awarding specialty pharmacy accreditation for a longer time, since 2001, first as part of its pharmacy program and then as a separate, distinct accreditation starting in 2008. Many health plans require accreditation of some sort when designating retail locations that members can go to to fill specialty pharmacy prescriptions. Manufacturers can have similar requirements, too.

There are a number of differences between the two accreditations. The URAC badge costs more to obtain, though no one at URAC will divulge that cost, and is awarded after a much more detailed examination of the pharmacy. The ACHC designation costs between $5,000 and $10,000, based on number of patients served and prescriptions written. José Domingos, CEO of ACHC, calls the two accreditations “apples and oranges, two different solutions.” He explains that ACHC is concerned with assuring positive patient outcomes—he calls that the “bigger picture”—rather than a detailed investigation of a pharmacy’s operations.

Tim Sailey, Director of DMEPOS, Pharmacy, and Sleep at ACHC, explains, “We don’t look at how the order is filled or how the medication is delivered. We look at the disease management process.”

ACHC has accredited about 200 specialty pharmacies, URAC 111. One advantage ACHC has is that it boasts “deemed” status from Medicare Part B, meaning it is easier for specialty and other outpatient hospital pharmacies to collect reimbursement from Medicare when that is an issue.

The larger, academic hospital pharmacies and health plan pharmacies appear to look more toward URAC because of its broader requirements, which may have particular resonance in the post–New England Compounding Center era. URAC has been accrediting specialty pharmacies for six years, according to Janice Anderson, RPh, URAC’s Director of Pharmacy Programs. URAC doesn’t provide a breakdown of how many of its 111 accredited pharmacies are at hospitals. Neither does ACHC. But in both cases, very few appear to be.

The University of North Carolina Health Care System, Fairview Health Services, and two or three more are the exceptions in the URAC listing. Most of the accredited are retail pharmacies. Those pharmacies that do earn the URAC specialty pharmacy designation must meet core and specialty competencies; there are 150 standards in the latter category. Those standards are initially proposed by an advisory committee made up of representatives of consumer and professional organizations, industry, and payers. The drug manufacturers do not participate, according to Anderson. Then public comments are sought, changes are made in the proposed standards, they are beta-tested, and they are finalized. URAC generally sends a nurse and a pharmacist to a pharmacy site seeking accreditation. That visit lasts two days. The two write recommendations as to whether the pharmacy should be accredited, and a review board makes the final decision.

URAC awarded a recent accreditation to Humana Inc.’s RightSource Specialty Pharmacy. Grady Pearson, PharmD, Director of Quality, RightSource, explains that accreditation required him to provide “very substantial documentation for all the things that we do.” RightSource includes a distribution facility, a “front-end” administrative facility, and a call center, all in Ohio. The process took six to eight months, states Pearson, who says the cost to Humana of accreditation is proprietary.

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information. URAC declines to make the size of the accreditation fee public, too.

The University of Illinois Hospital and Health Sciences System is considering obtaining a URAC specialty pharmacy accreditation. “We have begun a gap analysis, and are actually building services to align with URAC accreditation,” says JoAnn Stubbings, BSPharm, MHCA, Assistant Director of Specialty Pharmacy Services at the University of Illinois at Chicago College of Pharmacy, Ambulatory Care Pharmacy Department. “We’ve been in touch with URAC and expect to get it soon.”

The UIC outpatient clinics may have more access to specialty pharmaceuticals than many other hospital systems, though not the full gamut, because 30 clinical pharmacists are positioned full time in the system’s transplant, oncology, dialysis, and other clinics. “We may be different from other health systems in that regard,” notes Stubbings, who has been involved with the UHC committee developing that specialty pharmacy network.

But access to some specialty pharmaceuticals often requires more than just the right accreditation. “We have URAC accreditation, but, yes, we still have access problems,” notes Kyle Skiermont of Fairview. “Accreditation isn’t the end-all; it is becoming more of a requirement to even start a conversation.”

The growing importance of accreditation explains the establishment of the Center for Pharmacy Practice Accreditation (CPPA). It is the joint effort of the American Pharmacists Association, National Association of State Boards of Pharmacy, and American Society of Health-System Pharmacists. Lynnae Mahaney, BSPharm, MBA, FASHP, Executive Director of CPPA, says she hopes to have a specialty pharmacy accreditation program up and running by the end of 2014. It will only accredit pharmacy practices, making it a bit different from URAC and ACHC, which accredit numerous health care settings. “We understand we need a competitive, marketable accreditation program,” Mahaney states.

She has been talking with payers, who will be crucial to the accreditation program’s success. The question is whether UnitedHealthcare and the Blues, for example, will ease their mostly exclusive dependence on OptumRx and Prime, respectively, and allow CPPA-accredited pharmacies to fill specialty prescriptions for UnitedHealthcare and Blue Cross Blue Shield plan members.

URAC and ACHC accreditation haven’t always helped hospital pharmacies wrestle control of specialty prescriptions from the hands of health insurers. The CPPA will probably have to bring a much more alluring value proposition to the table.