

Specialty Pharmacy Services, Distribution, and Patient Care

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Growth and Scope of Specialty Pharmacy

In the US industry, specialty pharmaceuticals signify the swiftest growing section of the prescription drug market 1. They are making progress at the rate of 20% per year 1. The professional deals with specialty drugs. This paper will analyze the scope of specialty pharmacy with a discussion about its types along with the advantages and the services that it offers. There will also be the assessment of the risks and threats of this field to the professional 2. It will discuss the strategies that can be used in the future by the professionals to mitigate the risks and avail the opportunities as a pharmacist 2.

Defining Specialty Pharmacy

There is no precise definition of specialty pharmacy, although many pharmacy organizations have tried to define it. These were “The American Pharmacists Association (APhA), Specialty Pharmacy Association of America (SPAARx) along with the Association of Managed Care Pharmacy (AMCP) and National Association of Chain Drug Stores (NACDS). It focuses on high-cost, high-touch medication therapy for patients 3. The patients that come under specialty pharmacy suffer from some chronic or genetic diseases 1. For example, “cancer, growth hormone deficiency, Hemophilia, Pulmonary hypertension, AIDS, multiple sclerosis and rheumatoid arthritis,”etc. 1. They have an unmet need for therapeutic interference. Treatments in specialty pharmacy array from oral intake to injectable and biologic produce pharmaceuticals 1. The Specialty Pharmacy includes all the services related to specialty pharmaceuticals comprising both distribution and dispensing 2.

Characteristics of Specialty Drugs

These drugs in the US account for 15% of pharmaceutical spending with 15 to 20 % annual growth 4. The drug producer, dispensary, hospital, and others may or may not take it as a specialty drug. A specialty drug possesses the following characteristics. It treats complex, chronic or rare diseases 5. It is a high-cost drug that exceeds \$10,000, and its costs annually reach \$100,000 5. It has a high cost per patient. It is not available widely, but it involves exclusive and limited distribution 2. There are also special administrative requirements for it regarding storage; handling 5. There is the need to have special storage 5. There is no substitute available for these products. When the product gets mature, its utilization increases along with the price.

Professional Opportunities and Practice Challenges

It is a growing field, and it also offers challenges while working in the practice environment 4. This area also appeals to professionals because of its work schedule. Suppose offers flexible work schedules and even the facility of working from home 4. A specialty pharmacist gets the choice of working in different settings 4. He may work in specialized pharmacies that only deal with specialty drugs 4. There is a further opportunity for work; he may work in administration, medication therapy management, patient activism, and therapy acquiescence. He also has the choice of working in different health systems 4. There are also traditional retail settings for working. Specialty pharmacy performs these functions. They make available all the specialty medications. Arrange and manage the skilled and well-informed clinical support teams, ensure the patient-care synchronization and acquiescence monitoring, provide the dexterity of home-care services, and all the billing and reimbursement management 4.

Centralization of Specialty Pharmacy Services

In the health system pharmacy, the chief pharmacy officer makes the decisions. The CPO was in a dilemma of having the constant challenge of choosing the services that needed to be centralized 2. These decisions were getting more importance in the settings of large systems, as those big systems involve a massive investment of time and money 2. The decision of the centralization system also includes the pro forma financial statements analysis 2. While making the decision, the focus should also be on the probability of success 2. Cost is also an important driver for this ruling 2. The standardization reduces the costs 2. With this, the unproductive time gets less than 2. The centralization also offers risk tolerance 2.

Historical Development of Specialty Pharmacy

The history of the specialty pharmacy has different eras. There is a brief overview of these eras. Before the 1940s, the practice of pharmacy started as a reaction to the reforms that emerged in the educational and industrial sectors 6. The healthcare delivery system is also responsible for this. This practice began in the US during the 1920s 6. During this period, it was a marginal profession, as people were entering into this profession due to appreciation rather than formal education. The pharmacists were performing various roles from the ones that they are performing today. The pharmacist's function was then to handle and manage the remedies in common use. These were engaged in the distribution and wholesale manufacturing of medical drugs. At that time, there was no clear distinction between prescription and nonprescription drugs. The pharmacist was also supposed to perform the doctor role especially when it related to rural or underdeveloped areas. Due to this practice, they used to keep the proper stock of every drug or medicine that they wrote or suggested in the prescription.

Educational Reform and the Flexner Reports

In 1915, the US government sponsored the studies conducted in series; these are known as “Flexner reports.”⁷ These reviews also covered pharmacists. These were critical to the health care professionals and their education.⁷ In these reports, these pharmacologists came under the discussion about whether they are necessary to be a part of the health care system or if there is no need to have them in this system.⁷ The report concluded with the stress on the formal education of these people. Another study that was done by “ACCP” also supported it. It provided the basis for having a four-year bachelor’s degree for these people before entering into this profession.

Professionalization of Pharmacy Practice

Till the 1940s, this profession was equipped with people having all the required qualities and the education that was recommended (Flexner reports) before this era.⁷ Due to having fulfilled all the conditions, this profession started making tremendous progress between the 1940s to 1960s. The federal government’s work also supported all this. They were making massive investments in this field to maintain the quality in every aspect.⁶ Even for this purpose, there was massive funding for the establishment of the hospitals. These practices, on the one hand, improve the quality of the health field, but on the contrary, they diminish the role of pharmacists during this development. Their role also got at the backend due to the advancements in technology and because of the societal change in behavior.⁶ Now society was demanding a uniform composition in medical drugs. The educational institutions showed their reaction to the reduction of the roles. They started developing their curriculum and included all the improved technical and scientific studies, required for them. There was the memorization of the chemical and physical nature of the drugs.

Prescription Regulation and Role Definition

The ambiguity of their roles in the field became clear with the “Durham-Humphrey Amendment.” It was made compulsory to have a legal prescription before the distribution of the drugs. The American Pharmaceutical Association developed a code of ethics for this profession. According to this, pharmacists must not have any discussion related to the therapeutic effects of the medicines. Their role was defined with a restriction on the distribution of the drugs. Congress passed the Health Maintenance Act in 1973. This act serves as the basis for the incorporation of the roles of pharmacists in the health care delivery system. Now they started playing roles in Pharmaceutical Care.

Transition to Medication Therapy Management

This role was changed to medical therapist management. Due to the advancement in payment reforms, healthcare providers moved towards specialty patient management and therapy outcomes.

It gave rise to the specialty pharmacy industry. In the beginning, there were supportive programs that were designed to enhance the clinic's relationships with UW Health Pharmacists 8. With the passage of time, the focus shifted to the improvements in patient outcomes. Based on this focus the first program was started in January 2005.

Five Domains of Specialty Pharmaceutical Care

There are five domains of pharmaceutical care. Specialty pharmacies are different from conventional medicines in coordinating many aspects of patient care and disease management 9. They are premeditated to distribute medicines with specified management, storing proficiently, and deliver necessities with consistent developments that certificate frugality of scale. Specialty pharmacies are too intended to recover medical and financial consequences for patients with multifaceted, often enduring, and infrequent circumstances, near interaction and organization by clinicians. Healthcare professionals work in specialty pharmacies to deliver patient teaching, assist in safeguarding suitable medicine usage, endorse devotion, and make efforts to evade needless prices. Additional provision schemes coordinate allotment of info surrounded by clinicians handling patients and assist patients in finding capitals to offer financial help with out-of-pocket expenses "1.

Risk Management

1. There is risk management by having the system of data collection, review of the prospective drug utilization, documentation of all the therapeutic interventions and procedures, management of over-the-counter medical history, reporting to FDA for adverse drug events, if any, awareness of different drug interaction 5

Patient Advocacy

2. Under pharmaceutical care, they perform patient advocacy. If the patients face any social, economic, or psychological barriers to drug therapy, these are advocated by specialty pharmacists. They work on the removal of these barriers and develop positive relationships with the patients. One example of this is telephonic to patients about the medication orders.

Disease Management

3. They play a role in disease management. In this context, they used to provide information to the patients on how to manage their disease conditions. For this purpose, they also monitor the patient's progress.

Marketing of Care Services

4. They do the marketing for the care services that they provide. For this, they go and meet different prescribes and participate in professional associations.

Business and Staff Management

5. They also take the help of the technicians and other staff regarding all the management. And play their role in overall business management.

Stakeholders in the Specialty Pharmacy Market

There are many stakeholders in the specialty pharmacy market 3. These are MCOs, PBMs, Pharma Manufacturers, Wholesalers GPOs, distributors GPOs, Specialty prescribers, specialty Rx pharmacies, and physician's hospitals 3. All these key stakeholders benefit from the SPs in many ways. In the US, three companies have controlled two-thirds of the revenues of the pharmacy industry 3.

Cost Management and Patient Access

The specialty pharmacy has certain advantages: 1. This pharmacy provides two key deliverables and two major benefits: 1. These are the contrivance of managing the costs aimed at patients. Cost often develops a major fence on the exposure of specialty medications to tiered pricing¹. These deliver the products to the efficient channel as compared to the traditional models that deliver the products through less efficient means 1. They have a very critical reimbursement role not only in providing the medicines but also in controlling the costs through efficient reimbursement 1.

These medications are considered the most expensive drugs 10. Their prices range from several thousand to several hundred thousand dollars per year 10. However, the specialty pharmacist makes it easy for the patients to afford them. By having a specialty pharmacist, there are no worries about the distribution costs; these get eliminated. They have a link with the reimbursement hub that gives the advantage. These medications may have prolonged life in some cases. They often give challenges for their use. For this, the patients also get trained by them about how to have the drugs by themselves. These specialists also help with the side effects that sometimes prove fatal.

Distribution Channels and Reimbursement Barriers

There are many distribution channels in the markets for these drugs. But these channels are not easy to approach 11. Patients using Specialty drugs often remain tense with reimbursement obstacles 11 as these medications have limited availability and selected supply 5. Pharmacists help the patients

having the timely delivery of these specialty drugs 5. This practice also benefits the producers 5. Restricting the drug to a limited number of users or distributors increases acquiescence 5. It also gives the manufacturers the opportunity to have a broad range of research conducted to improve the quality and the enhancement of these drugs 97.

Operational and Distribution Services

There are many operational services that cover the distribution activities 6. All these repeats and again many times. The pharmacists then outsource these functions that reducing the costs 6. Due to their effective presence in the market, many copay organizations get partnerships with these specialty pharmacists, to play their roles in providing these benefits to the end users 6. These even offer financial solutions to the patients for having these expensive drugs for a long time 9. These, along with the pharmacy and the patient, efficiently initiate the patient on therapy 4. These network relations were fostered by these three participants. They have developed the portals so that the patients can trace the status of their application, can go for funding timely, the time for approval reduced, and the filling and refilling of the medications become accessible 6. These portals, on the other hand, also allow the patients to keep track of their treatment, including updates about the treatment, visit schedules to the physicians, and the timing of medicines and injections 6.

Funding Monitoring and Patient Follow-Up

Specialty pharmacists not only initiate the process with the patient, but they also keep track of patients for the medications 6. For this purpose, they monitor and maintain the required funding 6. For this, they use two methods. Firstly, they maintain the funding balances to avoid unanticipated funding lapses. For this purpose, these have started providing their adherence programs and have engaged the copay organizations to provide supplementary services in this regard 6. Secondly, they request the status update of the patients who do not get the delivery of the medicines within the anticipated time interval. With this, they anticipate the discrepancies in that particular case. They also track and analyze the results of the treatments for the patients. They ensure patient adherence programs.

Categories of Specialty Drugs

There are three types of specialty drugs. There are self-administered drugs that have Rx benefits. There are office-administered drugs that have the Med. benefits. The third category is the home-infused drugs that have both these benefits combined.

Referral Billing and Distribution Workflow

There are five stakeholders in this process. Patient, MD, SPP, Health plan, and the retail pharmacy. MD writes RX to the patient and sends the referral to the SPP. SPP also sends the RX to the patient. SPP sends the bill's plans to the health plan organization. The patient, after receiving the Rx from the MD, goes to the retail Rx, which is the retail pharmacy. The pharmacy, after planning the bill, sends it to the health plan organization.

Specialized Patient-Care Services

They provide the patients with special pharmacy services and special care services 4. They give the full range of services to improve and maintain the quality along with the safety of the procedures 4. These services also make the patients affordable. These services are specifically designed for the small population 7. These are not static populations, but these also grow with time. As the patients suffer from complex services that are chronic, the nature of the services should be special to them. Their services fall into three categories. They give the patient's health care provider access 6. They provide them the services of consultations with the physicians 6. Throughout the treatment, they make sure of the availability of the staff. They give them care management services to meet their unique needs 6. They provide them the multiple protections on every ground to endure their safety 6. Before the start of the treatment, there is a review of the patient's medical record. This gives disease-specific information. The last prescription gives the direction for the starting of procedure 1. All the activities get documented through process 1.

Round-the-Clock Clinical Support

Specialty pharmacists provide the services to the patients 24/7 9. They provide comprehensive patient care 6. They have a pool of specially trained chemists, nurses, and clinicians that are available around the clock 7. They work for the delivery of the nurse or the pharmaceutical on call 9. They provide the overnight delivery of the medication to any place, whether it is the office, the home, or any other place 6. They give them registry capabilities 5. They assist them all through the process 5. They give the patients educational services 5. These can be related to their disease, particular medication, etc. 5. They have special training to provide an understanding of different disease states so that they can make use of the drugs effectively 5.

They give better reimbursement services than the traditional channels 4. They make relationships with the care providers and the patients and also educate them on dealing with the patients 4. They design online support programs for patients 4. They in the market also provide marketing services in the pharmacy industry 4.

Services for Physicians and Care Providers

They also provide services to physicians 6. They give them clinical extensions to their offices. They ensure their compliance management 6. They provide them with the delivery of the customized dose. They provide the coordination in the distribution channels to the physicians 6. They also give assistance in billing as well as in coding 4.

Financial Assistance and Patient Support

These facilitate the eligible patients to have financial assistance 4. They develop the patient backing programs 4. They arrange for the services of the insurers for the patients. They perform the piloting of the services that they will provide. They directly work with them and make it possible for the patients to avail of the services 6. They try to sightsee every option. In this way, they give utilization management 4.

Benefits for Payers

Payor also benefits from their services 4. They fulfill their service expectation with the maintenance of the quality of the services 4. They give them competitive prices 4. They provide them with a customized program, especially working at group level 9. There are services provided to them regarding account management and marketing.

Services for Pharmaceutical Distributors

To the Pharma distributor, they provide the services of distribution of the products and give them the facility of the broad distribution 5. They have the supply chain management for them 5. This management includes the storage assistance, all the shipping facilities as well as the handling insurances 7. They facilitate the product not only on time but also confirm the delivery in optimal conditions 7.

Temperature Control and Risk Mitigation

As there is a need for temperature control while handling specialty drugs, they give them the services regarding temperature control. They perform the risk evaluation for them and provide them the mitigating strategies for their management 5. They also, in some cases, arrange direct interaction with the patients 5. These physician consultations allow the patients to have words with them regarding the side effects of the treatment, concerns related to the non-adherence, etc. they also arrange cognitive counseling for them 5. They also personally interact with the physicians and the

pharmacy and discuss the suffering of the patients regarding the use of medicine or treatments 5. Then, they provide this feedback to the patients also 5.

Contractual Relationships and Negotiation

The nature of contracts defines all these services: 1. They involve all the key players in this bonding. They maintain the pharmacy's collections and provide them the health plans 6. They become part of the negotiations that aim to bring the rate downs for medicines. Pharmacies then make themselves surrender to become part of these efficient systems that, in return, will also benefit them 1. They get their market share increased in this by having the increased sales that are being helped out by the specialty pharmacist. They use the principle of MAC for the determination of the prices. They all have this list as the result of the survey of wholesale prices that happen in the market.

Industry Growth and Career Prospects

With the expectation of growth at a rate of 20% to 23.5% annually, it has become the fastest-growing section of the industry 12. According to an estimation, by 2030, its number will rise to 40 % 12. Therefore, this field offers a wide range of opportunities to have a career or to pursue it to play an effective role in it 9.

Conclusion on Specialty Pharmacy Value

There is a great difference between customary and specialty drugs. Therefore, the nature of the services provided to them also differs. The needs of the industry established this industry sector as a response. There was a need for the efficient storage, maintenance, and the delivering of these specialty drugs due to their nature 11. These pharmacies lack the required technology and the expertise for their distribution. The nature of these drugs required the need of an intermediary so that the patients have admittance to them effortlessly 11. All this process is beneficial to both the patients and the industry, as it provides all the clinical as well as the operational services 13. Patients get treatments in infusion-based home centers, where it is easy to provide them the quality recovery 8. This field has achieved a lot and is still developing its aptitudes due to the changing needs of the patients, manufacturers as well as payers 13. The insurance company is playing their subsidiary roles; there is a need for a significant role played by them 13. Also, specialty pharmacies have the option of operating as an independent enterprise, or these can work under the influence of "PBM" 11 There is a need for future research addressing the exclusiveness of the role of pharmacists in the distribution and how these efforts can be coordinated 5. Future research can add to the existing body of knowledge on specialty pharmacy.

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