Louisiana Board of Pharmacy

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January 30, 2017

John A. Alario, Jr., President
Louisiana Senate
PO Box 94183
Baton Rouge, LA 70804
AlarioJ@legis.la.gov

Electronic Mail – Delivery Receipt Requested

Re: SCR 87 of 2016 Legislature

Dear Senator Alario:

SCR 87 of the 2016 Legislature, sponsored by Senator Johns, requested the Board of Pharmacy to study the issue of specialty drugs and specialty pharmacies as it relates to patient access to such drugs and make recommendations to the Louisiana Legislature in a report due no later than February 1, 2017.

The Board has completed its work and now submits the attached report. If there are any questions, please contact me directly at mbroussard@pharmacy.la.gov or 225.925.6481.

For the Board:

Malcolm Broussard

Malcolm J. Broussard
Executive Director

cc: Taylor F. Barras, Speaker, House of Representatives – BarrasT@legis.la.gov
Ronald S. Johns, Resolution Sponsor – JohnsR@legis.la.gov

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Specialty Drugs & Specialty Pharmacies

Prepared in Reply to
Senate Concurrent Resolution 87
of 2016 Louisiana Legislature

January 30, 2017

Malcolm J Broussard
Executive Director

Executive Summary

- SCR 87 of the 2016 Legislature requested the Board of Pharmacy to study and make recommendations regarding the use of the terms '*specialty drug*' and '*specialty pharmacy*' and whether revisions to present laws, rules or regulations were necessary to ensure the terms are consistently used in Louisiana in such a way as to not inhibit patient access.
- The U.S. Congress adopted the FDA Amendments Act of 2007 which authorized the federal Food and Drug Administration to require drug manufacturers to submit and implement Risk Evaluations & Mitigation Strategies (REMS) as part of their application to the FDA for their approval of the drug product, to ensure the drug's benefits will outweigh the risks.
- In their pursuit for drugs to cure diseases, American drug manufacturers employ high level technology, producing drug products that are more complex and costly than older medicines. Some of these newer drug products may require special handling, or perhaps more extensive clinical monitoring to prevent adverse reactions. Other special procedures may be required as part of REMS requirements imposed by the FDA. The term 'specialty drugs' has been coined to generally describe such drugs, to differentiate them from more traditional medicines.
- Pharmacies licensed by the board make business decisions as to which medicines to stock and dispense. Some of the special handling or other procedures required to dispense specialty drugs may have additional costs including additional professional health care practitioners. Pharmacies may elect to include specialty drugs in their inventory. Some have elected to specialize in the dispensing of specialty drugs, and many of these pharmacies have described themselves as 'specialty pharmacies'.
- Specialty drugs are expensive, constituting 40% of the $310 billion spent for drugs in the U.S. in 2015; the projection is for that percentage to reach 55% in the year 2020.
- Pharmacy benefit managers have begun to limit their reimbursement for dispensing specialty drugs to specialty pharmacies or other pharmacies who have achieved additional accreditation beyond state licensure. These decisions have an adverse impact

on patient access to specialty drugs and limit their freedom of choice for their own pharmacy.

- The board offers three recommendations and a legislative proposal to accomplish those recommendations:
  - The term 'specialty drug' should be defined in terms of any unusual handling requirements or other special procedures related to the drug product; however, there should be no drug cost or price parameters included in the definition.
  - Because every pharmacy licensed by the board can legally dispense specialty drugs, the board views the term 'specialty pharmacy' generically. The board suggests the term not be specifically defined.
  - The board is concerned for the newly-emerging requirements for voluntary accreditation of pharmacies beyond their state licensure as a qualifier for the reimbursement of dispensing specialty drugs; such requirements can have a chilling effect on the patient's freedom to choose their pharmacy.

Legislative Request

SCR 87 of the 2016 Legislature was authored by Sen. Johns and was enrolled on June 5, 2016. The resolution requested the Louisiana Board of Pharmacy to study and make recommendations regarding the use of the terms '*specialty drug*' and '*specialty pharmacy*.' The resolution noted these terms are used by different stakeholders in the pharmacy community, with each segment of the community creating their own definitions for the terms. Due to the inconsistent and unregulated use of these terms, the resolution noted there were obstacles preventing patient access to these critical medications. The resolution requested the Board to solicit input, recommendations and advice from entities or individuals knowledgeable about access to specialty drugs, including consumers, patients, medical providers, pharmacists, pharmacy benefit managers, pharmaceutical drug manufacturers, and insurers. The resolution closed with a request for the Board to submit a written report of its findings, together with any recommendations in the form of proposed legislation, to the Louisiana Legislature no later than February 1, 2017.

Drug Regulation

Within Section 8 of Article I of the United States Constitution, the United States Congress reserved unto itself the authority and power to regulate all matters relating to interstate commerce, which includes drug products. Although federal efforts to regulate the drug industry in this country date back to the *Food & Drug Act of 1906*, which prohibited the misbranding or adulteration of drug products offered for sale to the public, it was the *Food, Drug & Cosmetic Act (FDCA) of 1938* that established the federal Food & Drug Administration (FDA). The law required that agency to approve all drug products offered for sale in this country, and required approval to be based on the safety of that product. Subsequent amendments of the FDCA have included the *Durham-Humphrey Amendment of 1951*, which established the dual market system of 'prescription only' (Rx) and 'over-the-counter' (OTC), with the former required for those drug products for which safe use requires medical supervision. The *Kefauver-Harris Amendment of 1962* required the FDA to add efficacy of the drug product to its drug approval criteria. Although there have been other amendments to the FDCA over the years, for the purposes of this study, the *FDA Amendments Act of 2007* are most relevant, for their effect of authorizing the FDA to require a drug manufacturer submit and implement Risk Evaluation & Mitigation Strategies (REMS) to ensure a drug's benefits will outweigh its risks.

Drugs

The first drug products were derived from plants and other natural products. Pharmacists learned how to extract the active ingredient from the raw plant and then process that ingredient into a dosage form appropriate for use by the patient. These drug products, however, were primarily used for symptomatic relief; there were very few curative products at that time. During the late 1800s and early 1900s, there was a dramatic increase in drug research and development. Following World War II, American drug manufacturers merged technology with drug product production. New drugs and new dosage forms helped physicians to transition away from prescribing complex mixtures of ingredients toward ready-made single-ingredient medicines mass-manufactured by large drug companies. In the 1930s, about 75% of prescriptions required some compounding by a pharmacist; by 1950, that number dropped to about 25%. That trend

accelerated such that in 1960, that number was down to 4%, and in 1970, only one percent of all prescriptions required some compounding by a pharmacist.[1]

Drug research and development has continued to progress, enabling researchers to study plants and animals at the cellular level. The last 50 years have seen dramatic increases in the use of this biotechnology to create new drugs to improve the treatment of symptoms and, in some instances, to cure diseases. Some of these new drug products are available in traditional dosage forms such as tablets, capsules, or simple injectable products. However, some products consist of sterile solutions of large complex proteins to be administered by intravenous infusion.

Due to the nature of some of these newer drug products, the drug product itself may require special handling. Some of the products may have potentially dangerous side effects requiring laboratory or other types of monitoring during the course of therapy. Some of the products may require an unusual dosing regimen with or without supplemental medications. Some of the products require more extensive patient education over and above the patient counseling provided at pharmacies. Over the past decade, the term 'specialty drugs' has evolved to describe drugs with these characteristics, to differentiate them from traditional prescription drugs dispensed at most community pharmacies.

Specialty Drugs

The differentiation of specialty drugs has been used to highlight the additional resources required of pharmacies that dispense these medications. Such resources may include more refrigerator and/or freezer capacity to provide proper storage. The clinical monitoring might require access to laboratory data or other information systems not usually available in most pharmacies. The intensive patient education may require more time by the pharmacist or other health care professional associated with the dispensing pharmacy.

Specialty drugs are somewhat limited in number, compared to the totality of the prescription drug market, but the forecast reveals a healthy drug development pipeline. Biotechnology costs more to produce drugs, and moreover, manufacturers are raising drug prices at will. The number of diseases or medical conditions is relatively small, but the list is growing with new products. The American population is aging, and older patients take more drugs.

Spending on specialty drugs doubled in the past five years, reaching $121 billion in 2015.[2] By comparison, the total spending on medicines reach $310 billion in the same year. The increases in the spending for specialty drugs were driven primarily by treatments for hepatitis, autoimmune diseases, and cancer. The forecast for 2020 is for specialty drug spending to rise from its 40% of total drug spending to 55%.[3] Forty-three new drugs were launched in 2015; innovative products include the first cancer vaccine and new treatments for congestive heart failure in ten years. The late phase drug research pipeline includes 2,320 new products, 25% of which are oncology drugs. Of the 630 drugs in Phase II trials, 37% are specialty drugs.[4] Ten thousand Americans will celebrate their 65th birthday every day through the year 2030, when 20% of Americans will have reached that milestone.[5] Generally, older patients take more medications. CVS Caremark, a major pharmacy benefits manager, reported only 5.1% of its members used specialty drugs in 2015, but those members consumed 34% of the total health care costs for the year.[6]

Risk Evaluation & Mitigation Strategies (REMS)

Included in the FDA's evaluation of manufacturer's application for approval of a drug product is a consideration of the benefits of the drug for the intended patient population as well as the potential risks for adverse reactions. Some risks can be mitigated by implementation of additional procedures designed to assure optimal outcomes of drug therapy. Examples of REMS that could be implemented by a drug manufacturer include, but are not limited to, the following:

(1) Medication Guide and/or Patient Package Insert, which are documents containing additional information to help patients understand and manage their drug therapy, and they are required to be delivered to the patient at the time of dispensing the drug product.

(2) Communication Plan, which could include educational materials, suggested treatment protocols, or other information designed to assure safe outcomes of drug therapy, with such information being directed to prescribers and/or dispensers.

(3) Elements to Assure Safe Use (ETASU) include a variety of procedures designed to assure the patient's drug therapy is prescribed, dispensed, and monitored in such a manner to assure the safe use of the drug product, e.g.,

(a) Drug X will be prescribed only by prescribers who have been specifically certified by the manufacturer (or their agent) to prescribe that drug product;

(b) Drug X will be dispensed only by pharmacies which have been specifically certified by the manufacturer (or their agent) to dispense that drug product;

(c) Drug X will only be dispensed to patients with documentation of safe-use conditions, which places requirements on prescribers and/or dispensers to document the patient can safely receive and use the drug;

(d) Drug X will only be administered to patients within certain healthcare facilities where emergency medical resources are available, e.g., hospitals, outpatient surgery centers, ambulatory infusion centers, etc.;

(e) Manufacturer will ensure that patients receiving Drug X will be monitored by their prescriber or dispenser monthly for the duration of treatment with Drug X and for one month following discontinuation of Drug X; and/or

(f) Manufacturer will ensure that Drug X will only be dispensed to patients who are enrolled in the manufacturer's REMS registry.

(4) The REMS Implementation Plan includes the establishment of a secure database containing necessary information for all entities included in the plan, including drug distributors, pharmacies, prescribers, and patients receiving the drug

When the FDA approves a manufacturer's drug product application with REMS elements described therein, the manufacturer is required to implement and maintain the REMS plan. The enabling legislation established severe financial penalties for noncompliance with REMS plans; moreover, continued noncompliance with REMS requirements could render a drug product misbranded, which immediately disqualifies the drug product from being dispensed in any pharmacy.

By the end of Calendar Year 2016, approximately 75 drug products were identified by the FDA as having FDA-approved REMS systems in place.[7] The nature of the drug products varied widely and included a human insulin product as well as antidepressants, antipsychotics, and several drugs used for the treatment of different types of cancer. Some of the drugs are only

available in oral dosage forms such as tablets and capsules, while some of the drugs are only available as injectable dosage forms.

Pharmacies

When the owners of a community pharmacy implement their business plan, their acquisition of a permit from the Board of Pharmacy authorizes their pharmacy to purchase both prescription medications as well as OTC drugs and then offer them for sale to the general public. Since no single pharmacy could possibly keep in its stock every dosage form or strength of every drug product on the market, the pharmacy owner must make a business decision as to which drugs to maintain in their operating inventory. The drug distribution supply chain is well-developed in this country, meaning that most community pharmacies can place an order from a supplier for a drug not routinely stocked and receive it either the next day or certainly within a few days.

Every pharmacy is required to have adequate storage space for its drug inventory, as well as refrigerators for those drug products requiring such temperature controls. Beyond these minimum requirements, some pharmacies opt to include other special patient care areas in their pharmacies, e.g., patient counseling booths, private office space for extended consultations or medication administration, or classroom space for neighborhood health instruction events.

Every pharmacy must have a pharmacist designated as the Pharmacist-in-Charge. Beyond that pharmacist, the pharmacy must have an adequate staff (pharmacists, technicians, and clerical personnel) appropriate for their business operation. Depending on their business plan, some pharmacies opt to hire other medical professionals, e.g. nurses or phlebotomists. As an alternative to hiring other medical professionals, some pharmacies establish collaborative relationships with other entities, e.g., home health agencies, to have access to those medical professionals.

When a patient requires a medication for which the FDA has required the manufacturer to implement a REMS plan, the pharmacy should be able to comply with most of the potential risk mitigation strategies included in the plan, with the possible exception of those drugs requiring they be administered in healthcare facilities with emergency medical services available. If the pharmacy does not have, or cannot obtain, the resources necessary to comply with the REMS

requirement, the pharmacy should advise the patient and prescriber to arrange for a transfer to another appropriate provider.

Within the total number of community pharmacies in the country, many of them choose to operate as neighborhood pharmacies, catering to the full spectrum of pharmaceutical needs of their customers. Other pharmacies choose to operate as high volume prescription shops, turning away prescriptions that require compounding or other special handling. More recently, we have seen a growth in the number of pharmacies that choose to forego traditional prescription processing and specialize in prescriptions that require compounding or perhaps other special handling. Over time, some of these pharmacies have elected to describe their operations as specialty pharmacies.

While there is no single universal legally recognized definition of the term specialty pharmacy, several organizations have defined the term for their own particular constituencies.

- The National Association of Specialty Pharmacies describes a specialty pharmacy as a state-licensed pharmacy that solely or largely provides only medications for people with serious health conditions requiring complex therapies. These include conditions such as cancer, hepatitis C, rheumatoid arthritis, HIV/AIDS, multiple sclerosis, cystic fibrosis, organ transplantation, human growth hormone deficiencies, and hemophilia and other bleeding disorders. In addition to being state-licensed and state-regulated, specialty pharmacies should be accredited by independent third parties such Utilization Review Accreditation Commission (URAC), the Accreditation Commission for Health Care (ACHC), the Center for Pharmacy Practice Accreditation (CPPA), or The Joint Commission (TJC), to ensure consistent quality of care.[8]
- The State Patient Access Coalition, an organization representing manufacturers of specialty drugs and specialty pharmacies, describes a specialty pharmacy as a pharmacy that provides the services and management necessary to ensure optimal patient health outcomes when using a specialty drug, including but not limited to, clinical monitoring, patient training, compliance assistance, and specialized product handling and administration requirements.[9]

- The Center for Pharmacy Practice Accreditation, an accreditation organization which offers voluntary accreditation services to pharmacies, describes a specialty pharmacy practice as a pharmacy practice created (1) to manage the medication access and handling requirements of specialty pharmaceuticals, including dispensing and distribution, and (2) to provide clinical management services for patients with chronic, serious, life-threatening and/or rare disease or conditions receiving specialty medications aimed toward achieving the desired patient therapeutic and economic outcomes.[10]

Through its legislative mandate to regulate the practice of pharmacy, the Board is authorized to establish different classifications of pharmacy permits. With one exception, the primary parameter used by the Board to differentiate pharmacies is the locale of its primary clientele. The Board currently issues pharmacy permits in the following classifications:

- Community permits are issued to both independently owned and chain pharmacies serving the general community population.
- Hospital permits are issued to pharmacies located within hospitals and they are restricted to serving patients of a hospital (in-patient and out-patient).
- Institutional permits are issued to pharmacies located within healthcare institutions, now primarily the methadone treatment centers.
- Nuclear permits are issued to nuclear pharmacies, which may be located in any setting approved by the La. Dept. of Environmental Quality and they are limited to the preparation and distribution of radioactive medications used for both diagnostic and therapeutic purposes.
- Penal permits are issued to pharmacies located within penal institutions and they are restricted to serving offenders/clients within those facilities.
- Charitable permits are issued to pharmacies owned and operated by charitable institutions and they are required to dispense their medications free of charge to qualified indigent patients.
- Nonresident permits are issued to pharmacies located in other states to facilitate their conduct of business in this state.

Community and hospital pharmacies have been dispensing specialty pharmaceutical

products to their patients for several years. Since every pharmacy licensed by the board is legally authorized to dispense specialty drugs, and the resources required to properly manage specialty drugs are within the purview of the owner of the pharmacy, there does not appear to be sufficient basis to establish a separate permit classification for specialty pharmacies.

Patient Access to Specialty Drugs

Manufacturers of specialty drugs have an interest in making sure the pharmacies that dispense specialty drugs have the appropriate resources to manage the REMS requirements attached to their drugs. In some cases, they have established a limited distribution system for their specialty drugs, to ensure they can monitor the pharmacies' compliance with the REMS requirements. Such limited distribution systems can create patient access issues, or at the least, compromise the patients' freedom of choice for their pharmacy services.

Given the high cost of many specialty drugs, insurance companies and other third party payors, including pharmacy benefit managers (PBMs), have a financial interest in making sure the pharmacies that dispense specialty drugs are competent to do so. Some of these stakeholders have begun to require the pharmacies, which are already licensed and regulated by the state, to acquire voluntary accreditations from URAC, ACHC, CPPA, or TJC, as a condition of reimbursement for dispensing the specialty drug. The requirement for the acquisition of additional credentials beyond the state-issued pharmacy permit can create patient access issues, or at the least, compromise the patients' freedom of choice for their pharmacy services. That some PBMs operate specialty pharmacies in competition with other pharmacies has raised questions of transparency in their operations.

In the absence of a single universally-accepted definition of specialty drugs, some PBMs have adopted their own definition of that term, and some of those definitions have included the element of the price of the drug. For instance, in 2008 the federal Centers for Medicare & Medicaid Services (CMS) established the parameter of $600 per month, i.e., drug products whose cost exceeded $600 per month would qualify as specialty drugs if so desired by the PBM. In a recent communication, CMS reported the proportion of Medicare Part D claims that exceeded the $600 threshold increased from 0.78% in Calendar Year 2012 to 0.95% in Calendar Year 2014, and further, that the proportion of Medicare Part D expenditures related to specialty

drugs increased from 10.27% in Calendar Year 2012 to 16.22% in Calendar Year 2014.[11] While the use of a drug cost parameter may not apply to a large number of drugs at this time, the recent trend of large price increases by drug manufacturers could have a negative impact on that current finding. A larger number of drugs qualifying for specialty drug status can create patient access issues, or at the least, compromise the patients' freedom of choice for their pharmacy services.

Recommendations

1. There is no single universally accepted definition for the term 'specialty' drug. While many stakeholders include a variety of elements related to special handling requirements, some stakeholders include a financial element relating to the cost of the drug. While the former may be reasonable, the latter is arbitrary at best. The board is of the belief that no financial element should be included in the definition of the term 'specialty drug.' The board has approved a legislative proposal to define the term 'specialty drug', and that proposal is appended to this report.
2. Since every pharmacy licensed by the board is legally authorized to dispense specialty drugs, there seems to be no rational basis to define the term 'specialty pharmacy.' That term can be used in a general sense by any pharmacy in their trade name. The board recommends no specific definition for the term 'specialty pharmacy.'
3. While voluntary accreditation programs can be useful in facilitating the adoption of best practices, the requirement for such accreditations to qualify for reimbursement of the dispensing of a specialty drug has a chilling effect on the patient's access to such drugs. Accordingly, the board recommends the adoption of a statutory provision that no entity shall establish definitions or require accreditations or licensure which effectively limit patient access to prescription drugs other than the appropriate governmental or regulatory bodies.

Notes

1. Hendrickson R et al. *Remington: The Science and Practice of Pharmacy*, 2005, p. 14.
2. *Medicines Use and Spending in the U.S. – A Review of 2015 and Outlook to 2020*. QuintilesIMS Institute. April 14, 2016. http://www.imshealth.com; accessed December 2016.
3. Ibid.
4. Ibid.
5. CDC Website. *The State of Aging and Health in America in 2013*; http://www.cdc.gov/aging; accessed December 2016.
6. Mesaros J. *Specialty Pharmacy Overview*. Portland, OR; September 13, 2016.
7. FDA Website. *Approved Risk Evaluation and Mitigation Strategies (REMS)*; http://www.accessdata.fda.gov/scripts/cder/rems/index; accessed December 2016.
8. NASP Website. http://naspnet.org; accessed December 2016.
9. Personal communication; Mr. Bill Speir; December 2, 2016.
10. *Specialty Pharmacy Practice Standards*. Center for Pharmacy Practice Accreditation. Version 1; January 5, 2015. http://www.pharmacypracticeaccredit.org; accessed December 2016.
11. CMS Website. Medicare Part D Specialty Tier. April 7, 2015. http://www.cms.gov; accessed December 2016.

HLS 17-

Regular Session, 2017

House Bill No. _____

By Representative _____

PHARMACIES: Defines specialty drugs and prohibits any entity from establishing alternative definitions for this term or adding any other requirements that will limit patient access to prescription drugs.

AN ACT

To amend and reenact R.S. 22:1852, relative to definitions, and to enact R.S. 22:1857.2, relative to access to specialty drugs.

Be it enacted by the Legislature of Louisiana:

Section 1. R.S. 22:1852 is hereby amended and reenacted to read as follows:

§1852. Definitions

As used in this Subpart, the following terms shall be defined as follows:

* * *

(11.5) "*Specialty drug*" means a prescription drug which meets all of the following criteria:

(a) The drug cannot be routinely dispensed at a majority of retail community pharmacies due to physical or administrative requirements that limit preparation and/or delivery in the retail community pharmacy environment. Such drugs may include but are not limited to chemotherapy, radiation drugs, intravenous therapy drugs, biologic

prescription drugs approved for use by the federal Food and Drug Administration, and/or other drugs that require physical facilities not typically found in a retail community pharmacy, such as a ventilation hood for preparation;

(b) The drug is used to treat complex, chronic, or rare medical conditions

(i) That can be progressive;

(ii) That can be debilitating or fatal if left untreated or undertreated; or

(iii) For which there is no known cure.

(c) The drug requires special handling, storage, and/or has distribution and/or inventory limitations;

(d) The drug has a complex dosing regimen or requires specialized administration;

(e) Any drug that is considered to have limited distribution by the federal Food and Drug Administration;

(f) The drug requires

(i) Complex and extended patient education or counseling;

(ii) Intensive monitoring; or

(iii) Clinical oversight; and

(g) The drug has significant side effects and/or risk profile

* * *

Section 2. R.S. 22:1857.2 is hereby enacted to read as follows:

§1857.2 Access to specialty drugs

A. No entity shall establish definitions, or require accreditation or licensure, effectively limiting access to prescription drugs, including specialty drugs as

defined in R.S. 22:1852, other than the appropriate governmental or regulatory bodies.

B. In addition to the penalties provided in R.S. 22:1860, any violation of the provisions of Subsection A of this Section shall be deemed an unfair or deceptive act and practice pursuant to R.S. 22:1961 *et seq*. and shall be subject to the penalties provided therein.