Current News & Views

*Monthly Updates Set for MS Drug* is the title of an article appearing on page B5 of the January 25, 2010 issue of *The Wall Street Journal*. According to WSJ staff reporter Thomas Gryta, “Biogen Idec Inc. will communicate with doctors once a month on the occurrence of new cases of a rare brain infection in patients using its multiple sclerosis treatment Tysabri®, as the biotech firm strives to find the right balance in keeping the medical and financial communities updated on that number.”

The article reported that these more frequent updates are the result of the drug’s “association with progressive multifocal leukoencephalopathy (PML),” a debilitating and often fatal condition. The article stated that the rate of infection has hurt the sales growth of the drug, which is key to Biogen’s future and that Biogen withdrew the drug from the market for 18 months beginning in 2005 after three patients developed PML.

In 2006, patient and physician demand for the drug resulted in the drug being marketed once again. In 2008, Biogen began providing regular weekly updates to the public after PML re-emerged.

Sales of this drug in 2009 was reported as more than one billion dollars.

*When Hospital Fees Catch You Off Guard* was posted on WSJ.com on November 25, 2009. The article was written by Anna Wilde Mathews and begins with the observation that patients visiting some doctors’ offices and urgent-care clinics were being billed as though they had gone to the hospital’s emergency room. The article states that hospitals were charging patients “facility fees” when they visited an outpatient facility owned by the hospital, such as urgent-care centers and the offices of doctors’ affiliated with the hospital.

In one of the reported incidents, a patient was billed a $654.44 facility fee by the hospital for an urgent-care facility visit. This billing was in addition to the billing received from the affiliated doctors group for $355.

*Internet Drug Sites.* The National Association of Boards of Pharmacy announced, in a press release dated 12/28/2009, that the association now lists more than 5,000 Internet drug outlets as *Not Recommended* on the association’s website. The press release stated that 96% of the total number of sites reviewed “have been found to be out of compliance with pharmacy laws and practice standards established in the United States to protect the public health.”

The association reported that 5,231 Internet drug outlets had been assessed to date, and that 5,008 of the sites were found to be out of compliance with basic criteria for legitimate pharmacy practice for the following reasons.

• More than 75% dispense drugs without a valid prescription.
• More than half accept a brief online questionnaire in place of a prescription. To be valid and to ensure patient safety, a prescription must be based on a legitimate patient-practitioner relationship that has included a face-to-face physical examination.
• Nearly 25% post a physical address located outside the U.S.

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• Nearly half do not provide any physical address. According to the WHO, more than 50% of medicines purchased over the Internet from sites that conceal their physical address are counterfeit.

• Nearly half offer foreign or unapproved drugs. Because these drugs are not subject to the quality and safety requirements of those approved for sale in the U.S. – or even of those approved for sale in other developed countries – their safety and efficacy are unknown.

• Nearly 20% do not have secure sites that protect patients’ personal and financial information.

Doctor Sentenced for Writing Prescriptions Over the Internet for People Whom He Had Never Met is the title of a press release issued by the United States Attorney General’s Office for the District of Massachusetts on November 4, 2009, and reports that a doctor licensed and practicing in Virginia “was sentenced today in federal court on charges that he wrote prescriptions over the Internet for people whom he had never met or examined, as well as tax evasion charges.”

The federal judge sentenced the doctor to one year and a day in prison, to be followed by three years of supervised release. In addition to the prison sentence, the doctor must make restitution to the Internal Revenue Service in the amount of $203,291.

The press release reports that between 2004 and 2007, the Virginia doctor issued between 50,000 and 100,000 prescriptions over the Internet for Soma and other drugs to individuals for whom he had never performed a physical examination and whom, indeed, he had never met. The doctor was paid between $5.00 and $7.00 for each prescription he issued based on a brief form completed online by individuals seeking prescription drugs.

The Virginia Medical Board fined him $10,000 for not personally: obtaining a medical or drug history, performing a comprehensive physical examination, providing information about the benefits and risks of the drugs prescribed, and initiating interventions and follow-up care.

Immunizations - Community Pharmacists and the Marketplace

The National Vaccine Program Office sponsored a public meeting of the National Vaccine Advisory Committee’s (NVAC) Adult Immunization Working Group on December 1-2, 1997 in Florida, to explore adult immunization programs in nontraditional settings. The purpose of the workshop was:

• to gain a better understanding of programs currently offering vaccines to adults in nontraditional settings;

• to identify potential benefits and challenges associated with administering vaccines in nontraditional settings;

• to identify additional nontraditional settings that could be explored and potentially used;

• to define areas where additional research is needed;

• to develop an effective immunization strategy integrating immunization programs in nontraditional settings with those in traditional settings; and

• to develop quality standards for immunization programs in nontraditional settings.

Workshop participants included members of the NVAC Adult Immunization Working Group and representatives from approximately 50 organizations. Pharmacy was represented by the American Pharmacists Association, CVS/pharmacy, Georgia Drug and Narcotics Agency/Georgia State Board of Pharmacy, Mississippi Board of Pharmacy, and the National Association of Boards of Pharmacy.

A report published by the National Vaccine Advisory Committee in 2000 stated: “Pharmacies in the United States are increasing their participation in vaccination activities. Pharmacists are functioning as a) vaccine advocates, by educating their clients about the importance of vaccines; b) vaccine facilitators, by hosting vaccine clinics in pharmacies; and c) vaccine administrators,
by vaccinating their clients. The American Pharmacists Association and CDC’s National Immunization Program have developed a training course to prepare pharmacists for active participation in immunization programs. Twenty-six states have statutes that permit pharmacists to administer vaccine."

The following benefits and challenges of having vaccines administered in non-traditional settings, such as pharmacies, were highlighted at the workshop by the American College of Physicians and the National Medical Association.

**Benefits:**
- increased access and convenience;
- reduced cost for vaccination; and
- increased awareness of the importance of vaccination

**Challenges:**
- ensuring that trained staff are available to treat potential adverse reactions to vaccines;
- keeping effective records;
- protecting health-care providers from liability;
- preventing fragmentation of care; and
- removing restrictive legal regulations

In 2009, Maine became the last state to remove legal barriers to pharmacists administering vaccines. Pharmacists who have successfully completed immunization training courses may now administer vaccines in their pharmacies in every state.

**Retailers Jockey to Market Swine-Flu Shots** appeared in the *MARKETPLACE* section of the December 29, 2009 issue of *The Wall Street Journal*. The subtitle of the article read *As Supply Grows, Drugstores and Supermarkets Offer H1N1 Vaccine, Aiming to Boost Traffic, Publicize In-Store Clinics*.

The article stated that "Pharmacies, supermarkets and other retailers are jockeying to become the go-to provider for swine-flu vaccinations, in a bid to attract more customers and, in many cases, promote their in-store health clinics." The reporter points out that while the vaccine is becoming more widely available, H1N1 infections have been declining for several weeks and demand has subsided.

A spokesman for a drug store chain quoted in the article stated that, "Right now there’s probably more supply than demand." A spokesman for a supermarket grocery chain that operates pharmacies stated that they clearly see potential opportunity in promoting the vaccinations in that the vast majority of pharmacy customers shop the rest of the store.

**Getting shingles vaccine easier** appeared in the February 8, 2010 edition of *The Columbus Dispatch*. The article stated that shingles vaccine can now be obtained in community pharmacies due to new rules adopted by the Ohio pharmacy board allowing trained pharmacists to administer this vaccine. The article included information on shingles and how the vaccine can reduce the likelihood of contracting shingles by 50%. Pharmacies offering the vaccine are encouraging customers who are 60 years of age or older to talk to their doctor to determine if they should receive the vaccine.
Continuing Education: Pharmacy Law

The Business of Health Care: Specialty Pharmaceuticals, Home Infusion Pharmacies and Pharmacy Technician Compounding

Goals. This issue of Law & Mortar begins a discussion of the laws and rules regarding specialty pharmaceuticals, infusion therapy and home infusion pharmacies, one of the many specialty pharmacies that currently plays a significant role in the delivery of pharmacist care in a constantly evolving health care delivery system.

Objectives. At the conclusion of this article, the participant should be able to:

1. outline the evolution of outpatient infusion companies and the services they provide;
2. list drugs commonly used in infusion therapy and explain restricted distribution programs;
3. describe the services of home infusion pharmacies, how they are licensed and how they are regulated under Ohio laws and rules; and
4. explain the regulations for qualified pharmacy technicians that allow them to engage in compounding.

The federal government implemented the Diagnostic Related Group (DRG) payment system for hospital care in the 1980s in an effort to contain health care costs. This payment method replaced the fee-for-service system for Medicare patients and paid hospitals a fixed rate per admission, regardless of the patient’s length of stay or the hospital’s cost to treat the patient. Accordingly, patients requiring long term drug therapy became a financial liability for acute care hospitals, and new business models were developed to ensure treatment for these patients in outpatient clinics, hospices, ambulatory care centers or in their homes.

In order to remain viable and survive, health care businesses must continually adapt and develop new products, services, and business models that will decrease costs, increase revenue, and enhance health care services when third party, government and private reimbursement programs threaten current business models.

One new model involves outpatient infusion therapy companies owned and operated by hospitals, physicians, corporations of health care practitioners, home health care businesses, pharmacy chains or for-profit corporations (private and public), and in one instance, an international medical products company. The services provided by outpatient infusion therapy businesses continue to grow and evolve with the increasing number of biotech drugs being developed and marketed by the pharmaceutical industry.

The pharmaceutical industry is one of the most successful health care businesses in adapting to the federal and state government and insurance company efforts to decrease health care costs by reducing drug costs for their beneficiaries. One of the business strategies of the pharmaceutical manufacturers is the establishment of divisions and/or purchase of companies that develop, manufacture and market biotech drugs.

These new biotech drugs are referred to as specialty pharmaceuticals. They require administration by injection or infusion employing different types of catheters. The development and production of these specialty pharmaceuticals are more expensive, and consequently less likely to be subjected to competition. These products are also less likely to be subjected to competition from generic equivalent products as patents expire.

An increasing number of these specialty pharmaceuticals require special handling and/or compounding by health care professionals. Many must be refrigerated or frozen in order to maintain their effectiveness prior to administration.

Some of the specialty pharmaceuticals require a physician or skilled infusion nurse
to safely administer and monitor the effects of the drug with lab testing. Infusion nurses have typically undergone advanced education and training for home or alternate-site administration of specialty pharmaceuticals, drugs and biologics.

Professional services provided by these nurses include assessment of the patient prior to initiation of home infusion therapy. This assessment is to determine if home infusion therapy is appropriate and may be successfully carried out under aseptic conditions in the home. If conditions are appropriate for home infusion therapy, these skilled nurses also provide education and training for the patient or caregiver to successfully administer the infusion therapy without the nurse being present.

**Infusion Therapy**

Infusion therapy includes the intravenous administration of drugs commonly used in hospitalized patients: antibiotics, antifungal agents, antiviral agents, chemotherapy agents, hydration solutions, pain management medications, and parenteral nutrition. Intravenous therapy now also includes specialty pharmaceuticals such as blood factors, corticosteroids, erythropoietin, inotropic cardiac medications, growth hormones, immunoglobulins and monoclonal antibodies such as infliximab (Remicade®) and natalizumab (Tysabri®).

Natalizumab is a recombinant humanized IgG4κ monoclonal antibody indicated for patients with relapsing forms of multiple sclerosis. It is considered a high risk drug due to the increased risk of progressive multifocal leukoencephalopathy. The distribution of this drug, therefore, is restricted by the manufacturer through a program called the TOUCH® Prescribing Program. The only health care entities allowed to prescribe, distribute, or infuse natalizumab are those prescribers and pharmacies associated with infusion centers registered with the program. Patients must also be enrolled in the program and meet all program conditions before the drug may be administered to them.

**Ambulatory Infusion Suites and Home Care Businesses**

An increasing number of home infusion therapy providers are now establishing and operating ambulatory infusion suites. The suite is a separate room where drugs are administered intravenously and clinical care is provided pursuant to a physician’s order by qualified nurses and pharmacists. These infusion suites may be owned and operated by home infusion pharmacies, home health care businesses, hospital clinics, or physicians predominately treating cancer and infectious diseases.

Continuous efforts in cost containment by health care payers have resulted in infusion therapy being provided at home by home health care businesses. An increasing number of these home health care businesses located in Ohio are including a home infusion pharmacy in their operations. Those that do not have a home infusion pharmacy may contract with a home infusion pharmacy to compound and provide the intravenous medication for administration by nurses. The nursing services may also include establishing the appropriate venous access devices required to administer the sterile parenteral drug prescriptions.

**Home Infusion Pharmacies**

The National Home Infusion Association provides the following definition of a home infusion pharmacy on their website (www.nhianet.org): A home infusion pharmacy is a “Pharmacy-based decentralized patient care organization with expertise in USP 797-compliant sterile drug compounding that provides care to patients with acute or chronic conditions generally pertaining to parenteral administration of drugs, biologics and nutritional formulae administered through catheters and/or needles in home and alternate sites. Extensive professional pharmacy services, care coordination, infusion nursing services and equipment are provided to optimize efficacy and compliance.”

In addition to providing and compounding prescriptions for sterile products, infusion pharmacies also provide the following
professional services: patient assessment and admission, education and training, care planning and coordination, care management by clinical infusion pharmacists, troubleshooting and treatment plan oversight, and other professional services needed to assure safe and successful treatment of the patient. The home infusion pharmacist is part of the patient care team that includes other health care practitioners and clerical specialists.

Home infusion pharmacies are one of the many closed-door specialty pharmacies that have evolved in the last 20 years due to economic forces impacting health care in this country. Home infusion pharmacies are not open to the public and only accept patients referred by their physicians, hospital discharge planner, case manager, nursing agency or the patient’s insurer.

Referrals are processed by an intake team that may include clinical staff, an insurance specialist and/or trained patient service representatives. Complete patient and prescription information must be gathered immediately since, in most cases, infusion therapy must begin within a few hours following referral. The referral and intake process must be accurate, thorough, and efficient. The intake team first evaluates the patient’s information and decides whether home infusion therapy is appropriate and will be therapeutically effective. The team’s insurance specialist or trained patient service representative will determine the total cost of the treatment, what costs will be covered, and those costs for which the patient is responsible.

Pharmacies providing home infusion services in Ohio are licensed by the pharmacy board as a FTHH (Fluid Therapy Pharmacy/Home Health Care) terminal distributor of dangerous drugs. FTHH type pharmacies are regulated by Ohio Revised Code (ORC) Chapter 4729. (Pharmacy Practice Act/Dangerous Drug Distribution Act), 3715 (Ohio’s Pure Food and Drug Law, and 3719 (Controlled Substances); and Ohio Administrative Code (OAC) 4729-31 (Fluid Therapy Pharmacies), 4729-4 (Pharmacy Technician Training Program), 4729-5 (Pharmacy Practice), and 4729-9 (Dangerous Drugs).

Paragraph (B) of OAC Rule 4729-31-01 states that a “fluid therapy pharmacy means a pharmacy where the primary purpose is to compound and dispense parenteral compounded sterile product prescriptions.” This paragraph also states that such pharmacies “must comply with the minimum standards for compounding parenteral or sterile product prescriptions as defined in rule 4729-19-04 of the Administrative Code.”

Home infusion pharmacies are commonly located in a business or industrial park. Home infusion pharmacies that are a part of a home health agency typically share the same facility and employees. These pharmacies include a reception area; an office for billing, human resources responsibilities and purchasing; a compounding area; and another area where legend devices, supplies and packing material are stored and received.

Paragraph (C) of OAC Rule 4729-19-04 outlines the physical requirements of the facility. The home infusion pharmacy must have a designated area for the compounding of parenteral and sterile products. Access to this area must be limited to authorized personnel and designed to avoid unnecessary traffic and airflow disturbances from activity within the controlled area. This designated area may not be used for any other purpose than the compounding and preparation of the home infusion prescriptions.

The designated compounding and preparation area must be of sufficient size to accommodate a laminar airflow hood or other primary engineering control devices that provide and maintain a class 100 environment during normal conditions; and provide for the proper storage of drugs and supplies used to compound and prepare sterile prescriptions. Proper storage includes appropriate conditions regarding temperature, light, humidity, sanitation, ventilation and security.

The home infusion therapy order includes the compounded sterile prescription, prescription devices, supplies and other drugs required for safe and effective treatment of the patient. The home infusion therapy
order is delivered by employees of the pharmacy (i.e., nurses or delivery personnel) or contracted couriers to the patient’s home or ambulatory infusion suite.

Paragraph (D) of OAC rule 4729-19-04 (Minimum standards for compounding parenteral or sterile product prescriptions) requires the responsible pharmacist to ensure that the compounded sterile home infusion prescriptions are shipped in packaging material that will not only maintain the sterility of the compounded prescription, legend devices and supplies, but also maintain the integrity of the compounded drug. Many of these drugs must be kept at a specific temperature during transport to the patient’s home.

If the specialty pharmaceutical is reconstituted at the pharmacy, the time of delivery and commencing of administration is often critical. For example, an infusion of Remicade® should begin within three hours of reconstitution, and must be administered over a period of not less than two hours using an infusion set with an in-line, sterile, non-pyrogenic, low-protein-binding filter (pore size of 1.2 micro-milliliters or less). FDA official labeling states that any unused portion of the infusion solution of Remicade® should not be stored for reuse.

In order for the drugs to be legally compounded and administered to the patient by qualified nurses, the home infusion pharmacist must first obtain and make a complete review of the patient’s medication profile before preparing all prescription orders that are required to carry out the prescribed infusion therapy in a safe and effective manner. These prescription orders are then faxed to the prescribing physician for his/her written signature.

The prescriptions must comply with pharmacy board rule 4729-31-02 (Prescriptions for sterile products). This rule states that the pharmacist may only dispense a fluid therapy prescription pursuant to an original patient-specific order issued by the prescriber. Paragraph (A) of OAC Rule 4729-31-02, however, also authorizes oral orders for sterile prescription products to be transmitted by a prescriber or an agent of the prescriber to a pharmacist, the only exception being prescriptions for Schedule II controlled substances. The oral orders must be recorded by the pharmacist and include the full name of the authorized personnel transmitting the oral order.

This rule further requires that the original signed order must be faxed directly from the prescriber to the pharmacy. The original signed order must remain with the patient’s records at the prescriber’s office or the institutional facility where it was issued. A facsimile from any location other than the prescriber’s office or the institutional facility where it was issued is not a valid prescription.

All drug orders for patients of a fluid therapy pharmacy must include, but are not limited to, at least the following information: name and address of the patient; name, strength, and dosage form of the drug; directions for use, including route of administration; date prescribed; prescriber’s positive identification; and the length of therapy or total quantity to be dispensed.

Once the signed prescription order for a compounded sterile product has been received by the home infusion pharmacist, he/she enters the order into the computer. The computer program prepares the prescription label and the mixing report (compounding instructions) for use in compounding the fluid therapy prescription. The compounded prescription products are all prepared according to drug-specific protocols developed by the home infusion pharmacy. The protocols are also specific regarding the patient’s age and medical condition.

OAC Rule 4729-31-01 sets forth the definition of a “compounded sterile product prescription” by referring to the definition of this term in paragraph (B) of OAC Rule 4729-19-01. In accordance with this definition, “compounded sterile product prescriptions” include but are not limited to the following preparations: total parenteral nutrition (TPN) solutions; irrigating fluids; ophthalmic preparations; and parenteral analgesics, antibiotics, antineoplastic agents, electrolytes, and vitamins.
OAC Rule 4729-31-03 (Labeling) requires the following information on a compounded parenteral product prescription label: pharmacy telephone number, name and address as it appears on the terminal distributor of dangerous drugs license; patient’s name; prescriber’s name; directions for use including the route of administration; dispensing date; beyond-use date; name of drug(s) and amount added; name and volume of parenteral solution; storage conditions; any cautions required by federal or state law; and quantity of drug dispensed, if appropriate. The label containing this information must be affixed to the container in which the fluid therapy prescription is dispensed.

Compounding Standards and Quality Assurance

OAC Rule 4729-19-04 sets very general minimum standards for the compounding of parenteral or sterile product prescriptions by referring to OAC Rule 4729-17-08 (Minimum Standards for an Institutional Pharmacy). This rule is relatively brief and addresses three issues in general terms: the library; drug inventory, fixtures, and space; and personnel.

Paragraphs (B) through (H) of OAC Rule 4729-19-04 outline more specific and detailed standards for pharmacies that compound parenteral or sterile prescriptions. Paragraph (B) requires that these pharmacies must prepare and maintain a policy and procedure manual regarding the compounding, dispensing and delivery of sterile product prescriptions. This manual is required to address the following issues at a minimum:

• a quality assurance program for the purpose of monitoring personnel qualifications, training and performance, product integrity, equipment, facilities, and guidelines regarding patient education;

• justification for the chosen beyond-use dates of compounded products; and

• the handling of cytotoxic waste, if applicable.

OAC 4729-19-04 (H) (1) addresses quality assurance programs that the home infusion pharmacy must develop and have in place regarding training and continued competency monitoring of all pharmacy personnel; verification of the accuracy of all compounding activities including inspection and testing of end products for microbial contamination, particulate matter and pyrogens; continued verification of the accuracy of all automated compounding devices; and the use of appropriate beyond-use dates for all compounded products.

Section (2) of Paragraph (H) of this rule requires environmental monitoring of all clean rooms and laminar flow hoods at least every six months to ensure that all systems are efficiently and effectively maintaining sterile conditions. Records certifying the operational efficiency must be maintained for at least three years.

Pharmacy Technician Compounding

One of the most significant regulatory issues concerning the compounding of prescriptions in Ohio is recent legislation requiring that only a pharmacist, pharmacy intern or qualified pharmacy technician may engage in the compounding of prescriptions. Ohio Revised Code section 4729.42 was enacted by the Ohio General Assembly in 2009 and the new statute became effective April 8, 2009.

ORC 4729.42 outlines regulations for a qualified pharmacy technician to engage in the compounding of any drug, packaging or labeling any drug; or preparing or mixing any intravenous drug to be injected into a human being. Qualified pharmacy technicians have submitted to and passed a criminal records check, and passed an examination approved by the pharmacy board. The purpose of the exam is to prove their competency in performing their services as a pharmacy technician.

OAC Rule 4729-4-02 establishes two types of exams approved by the pharmacy board. Paragraph (A) of this rule stipulates “examinations provided by a national pharmacy technician certification program that is accredited by the National Commission for Certifying Agencies (NCCA)” and exams provided by employers after being approved
by the board.

This paragraph also provides that information regarding the two national exams will be posted on the board’s website. Two national exams accredited by the NCCA have been approved to date: the PTCB (Pharmacy Technician Certification Board) exam and the ExCPT exam provided by the Institute for the Certification of Pharmacy Technicians (ICPT). The board’s website also provides the web links for the organizations providing these exams where applications and detailed information can be obtained regarding the exams (www.ptcb.org and www.nationaltechexam.org). These two national exams are designed to test knowledge and skills to practice in all pharmacy practice settings.

Paragraph (B)(1) of this rule provides employers with the opportunity to develop their own exams for approval by the board. “The employer shall ensure that the examination is of appropriate breadth and depth, clearly addresses the competencies required for a technician to safely and effectively work in that particular setting and shall include at a minimum the following:

• applicable employer’s practice areas specified in division (B) of revised code section 4729.42;
• pharmacy terminology;
• basic drug information;
• basic calculations;
• quality control procedures;
• state and federal laws, rules and regulations regarding the tasks that qualified pharmacy technicians may legally perform, the tasks that only pharmacists and pharmacy interns may legally perform, procedure for processing drug orders or prescriptions, drug record keeping requirements, patient confidentiality, security requirements, and storage requirements.

Sections (B) (2) through (5) of this rule spell out further criteria and requirements regarding employer-provided exams for certifying that their pharmacy technicians are qualified to perform any of the tasks required in their pharmacy. The employer must have procedures that ensure the security and integrity of the examination materials, describe the testing format, and define the successful completion of an examination which must be at least 75%. Record keeping and security of exam questions are also addressed in this rule.

The employer shall maintain examinations and scores of all employees who successfully pass for a minimum of three years after the employee ceases employment.

Qualified pharmacy technician examination submission forms are available on the board’s website (http://pharmacy.ohio.gov/whatsnew.htm).

The next issue of the Law and Mortar will continue discussing federal and state laws impacting home infusion therapy and home infusion pharmacies.