Dear Health Law Section Members:

The Section website has been updated with articles on significant developments in the health law arena that may be of interest to you in your practice. These summaries are presented for general information only as a courtesy to Section members and do not constitute legal advice from The Florida Bar or its Health Law Section. On behalf of the Section, I extend my deepest appreciation to the following volunteers who have generously donated their time to prepare these summaries for your review:

Martin Dix, Esq. ***Rodney Johnson, Esq.*** ***Adam Maingot, Esq.***

Sheryl D. Rosen, Esq.

Thank you.

Malinda R. Lugo, Esq.

You can download a copy of this month's update using the links below or read the updates in this article on the Section website.

LIFE SCIENCES

Board of Pharmacy-Compounding Pharmacies:

Effective June 22, 2014, Board of Pharmacy (Board), Rule 64B16-27.700(3)(g), Florida Administrative Code, requires all pharmacies that engage in office use compounding of sterile products intended for human use be in full compliance with 21 United States Code § 353b, which includes being registered as an outsourcing facility.

Reported by Martin R. Dix, Esq.

DEA-Tramadol:

On July 2, 2014, the DEA published in the Federal Register the final rule placing tramadol into schedule IV of the Controlled Substances Act. This rule will become effective on August 18, 2014. All regulatory requirements applicable to schedule IV controlled substances will apply to tramadol beginning August 18, 2014.

Reported by Martin R. Dix, Esq.

FDA Issues New Medical Device Substantial Equivalence Guidance

On July 15, 2014, the U.S. Food and Drug Administration (FDA) issued draft guidance that outlines when a medical device is substantially equivalent to another device and can receive abbreviated FDA review. According to the U.S. Food, Drug and Cosmetics Act, a new medical device is substantially equivalent to an existing "predicate" device when the new device:

- Has the same intended use as the predicate device; and
- Has the same technological characteristics as the predicate, or has different technological characteristics but is as safe and effective and does not raise different questions of safety and effectiveness than the predicate.

The new guidance focuses on the last step of the analysis – how FDA determines a device is as safe and effective as a predicate. The safety and effectiveness need not be identical. A new device can have increased safety and decreased effectiveness – or decreased safety and increased effectiveness – and still be considered substantially equivalent. When making these assessments, the FDA will weigh the benefits and risks of the new device versus the predicate. When considering benefits, the FDA will weigh:

- Type of benefit;
- Magnitude of the benefit;
- Probability of the patient experiencing the benefit; and
- Duration of the benefit.

When assessing risks, the FDA will consider:

- Severity, types, number, and rates of harmful events associated with use of the device;
- Probability of a harmful event;
- Probability of a patient experiencing one or more harmful events;
- Duration of harmful events; and
- Risk from false-positive or false-negative results (for diagnostic devices).

The draft guidance may be accessed at:

http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm404770.htm

Posted by Sheryl D. Rosen; edited by Adam R. Maingot

COMPLIANCE

OIG Advisory Opinion 14-05-Pharmacies.

The U.S. Department of Health and Human Services, Office of Inspector General ("OIG") issued an Advisory Opinion 14-05 on July 28, 2014, which addressed a pharmaceutical manufacturer's discounts to patients for a brand name medication dispensed by a mail order pharmacy. The program as described in the request would permit eligible patients to purchase the manufacturer's brand-name drug for a discounted cash price from a mail order pharmacy that contracted with the manufacturer where neither the pharmacy nor the patient sought reimbursement from any third-party payor, government, or private payor. The OIG ultimately concluded that it would not impose sanctions under the civil monetary penalties statute or the Federal Anti-Kickback Statute against either the manufacturer or the pharmacy in connection with the program.

Reported by Martin R. Dix, Esq.

OIG Advisory Opinion 14-06-Specialty Pharmacies

The U.S. Department of Health & Human Services, Office of Inspector General (OIG) recently refused to bless a specialty pharmacy's request to pay a per-prescription fee to retail pharmacies for "support services" to be provided in connection with prescriptions transferred to the specialty pharmacy (OIG Advisory Opinion 14-06). The opinion had enumerated eight services to be provided by the transferring pharmacy. The OIG found that the per prescription fee could influence the retail pharmacy's decision to transfer prescriptions, that the proposed arrangement implicated the Anti-Kickback Statute ("AKS") and posed more than a minimal risk of fraud and abuse.

The OIG stated that the AKS was implicated because the specialty pharmacy would pay a per-prescription fee for support services each time the retail pharmacy referred a specialty drug prescription. In most pharmacy-to-pharmacy prescription transfers, there is no accompanying payment. The OIG noted that the specialty pharmacy paid the retail pharmacy for support services only when a prescription was transferred. Thus, the OIG found that such per-prescription fee is "directly linked" to business generated by the retail pharmacy, and could materially influence the retail pharmacy's referral decisions (whether to transfer the prescription). While the OIG recognized that the retail pharmacy's support services may benefit care coordination, it noted that the AKS is implicated if "one purpose" of the remuneration is to generate referrals (the "one purpose" test). Though the specialty pharmacy argued that it was paying fair market value for the services, the OIG found that there was a significant risk that the per-prescription payments were compensation to the retail pharmacy for generating referrals, rather than solely compensation for services provided by the retail pharmacies.

Most states allow pharmacies that are either commonly owned or have a contractual arrangement to engage in central fill arrangements, whereby an originating pharmacy receives the prescription, the prescription is shared with a dispensing pharmacy which dispenses the medication either directly to the patient or back to the originating pharmacy (similar to the arrangement described in the opinion above). Generally in a central fill arrangement, there is a sharing of pharmacy duties and responsibilities and some sort of sharing of the reimbursement for the medication. Since many state pharmacy boards allow central fill arrangements, these were usually not viewed as an improper payment for a referral. The above opinion casts doubt on these arrangements where there is a split of the reimbursement and when the drugs are reimbursed by a federal health care program (The AKS only applies when payment is made under a federal health care program). At a minimum, pharmacies engaging in such arrangements should make sure that the arrangements are commercially reasonable and justified such that they would not be viewed as a mere referral arrangement. And, while excluding or "carving out" federal programs does not always remove the Federal AKS risk, in this instance excluding federally reimbursed prescriptions completely may help insulate the central fill arrangements, at least from federal law.

Absent from the OIG's discussion was that many state prescription transfer laws and regulations only apply to refills and not to the transfer of the original prescription.

Reported by Martin R. Dix, Esq.

FACILITY AND PROFESSIONAL LICENSURE

Florida Department of Health –Medical Marijuana – Rule 64-4, FAC

The Department is proceeding with proposed rules implementing the "Charlotte's Web" bill allowing 5 dispensing organizations in the state to dispense non-euphoric medical marijuana. The rules follow the convoluted statute's requirements allowing the low THC medical marijuana. Among the requirements are:

- Only 5 suppliers restricted to 5 regions in the state;
- If more than one qualified supplier per region applies, there will be a "lottery";
- Certified nurseries must own at least 25% of the business;
- Medical marijuana only dispensed to FL residents;
- $150,000 application fee and $5 million performance bond;
- detailed application, licensing and inspection requirements; and
- Successful licensees must start cultivation within 75 days of the award or must start distribution within 150 days.

Reported by Martin R. Dix, Esq.

Board of Pharmacy-Pharmacy Technician to Pharmacist Ratio

The Board of Pharmacy is proceeding with rule development to implement registered pharmacy technician to pharmacist ratios in various practice settings. The proposed ratios would be 3:1 in sterile compounding; 4:1 in a community pharmacy; and 6:1 in a data processing/mail order/central fill type setting. In contemplation of this possible rule change, the Board also proposed a rule on delegation and supervision of registered pharmacy technicians (64B16-27.4001) and revisited Rule 64B16-27.420 addressing delegable and non-delegable tasks.

Reported by Martin R. Dix, Esq.

PUBLIC HEALTH

2014 APHA Meeting. The American Public Health Association's (APHA) 142nd Annual Meeting, themed "Healthography: How Where You Live Affects Your Health and Well-Being," will take place in New Orleans, November 15–19, 2014, at the Ernest N. Morial Convention Center. The advanced registration deadline is October 3, 2014. Registration fees increase after October 3.

Reported by Rodney Johnson, Esq.