THE FLORIDA BAR HEALTH LAW SECTION
JANUARY 2014 HEALTH LAW MONTHLY UPDATES

The following are brief summaries prepared by section volunteers of new developments in Florida and Federal health care law that may be of interest to members of the Health Law Section. The 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.

THIRD PARTY PAYOR

Fight Against United Healthcare's Termination of Providers

Throughout the nation, and especially in Florida, United Healthcare is terminating participating providers from its Medicare Advantage network. United Healthcare has cited "significant changes and pressures in the health-care environment," and "pressure from the federal government" for launching its termination initiative. In an attempt to combat the terminations, Connecticut's Fairfield County Medical Association and the Hartford County Medical Association filed suit against United Healthcare seeking a temporary restraining order and a preliminary injunction to prevent United Healthcare from terminating Connecticut providers from its Medicare Advantage network.

On December 5, 2013 Judge Stefan R. Underhill, U.S. District Court for the District of Connecticut, entered a preliminary injunction against United Healthcare ruling that the physician organizations proved that they would suffer irreparable harm if removed from United Healthcare's Medicare Advantage network. Immediately thereafter, United Healthcare appealed the ruling, which is now pending before the United States Court of Appeals for the Second Circuit. Although the preliminary injunction was rendered in Connecticut, many Florida providers are paying close attention to the outcome of the case. Additionally, the Florida Medical Association (FMA) has signed on to a brief amici curiae arguing that the preliminary injunction was proper. Erin VanSickle, a FMA spokeswoman, was reported to have stated in an email, "The Florida Medical Association has a substantial interest in ensuring that United not be permitted to unilaterally terminate any physician, either in Connecticut or elsewhere, in the way it has sought to do." Oral argument before the United States Court of Appeals for the Second Circuit is currently set for January 21, 2014.

The impact of this ruling on Florida physicians can be followed at the FMA's UnitedHealthcare Action Center, which is located online at: http://www.flmedical.org/UHC.aspx

Submitted by R. David Evans

HIPAA

First HIPAA Settlement for Failure to Have Breach Notification Policies

On December 26, 2013, the U.S. Department of Health and Human Services Office for Civil Rights ("HHS OCR") announced that a Northeastern dermatology practice has agreed to pay HHS a $150,000 settlement related to potential HIPAA Security Rule violations. The settlement is the result of an investigation into the theft of an unencrypted thumb drive containing the protected health information of over 2,000 patients. OCR alleged that the medical practice did not conduct an accurate and thorough risk assessment of potential risks to the confidentiality of patient information until a year after the theft. Also, OCR alleged that the practice did not have written policies and did not train its workforce on breach notification requirements until several months after the theft. This is HHS' first settlement arising from the failure to have policies in place to address the breach notification requirements of the Health Information Technology for Economic and Clinical Health (HITECH) Act enacted in 2009.

More information is available at:
http://www.hhs.gov/ocr/privacy/hipaa/enforcement/examples/apderm-agreement.html

Accretive Health, Inc. Data Breach Leads to 20 Year Settlement with FTC

On December 31, 2013, the U.S. Federal Trade Commission ("FTC") announced that Accretive Health, Inc., ("Accretive") agreed to settle charges that the company's inadequate data security measures exposed sensitive consumer information to the risk of theft or misuse. Accretive provides medical billing and revenue management services to hospitals. In 2011, one of Accretive's unencrypted laptops was stolen from an employee's car. Under the settlement agreement, Accretive must establish and maintain a comprehensive information security program designed to protect the security, confidentiality, and integrity of personal information of consumers. Accretive must have the program evaluated initially and then every two years by a certified third-party. The settlement will be in force for twenty years. This is not the first settlement arising out of the theft of the unencrypted laptop. In July 2012, Accretive settled with the Minnesota Attorney General, who sued the company alleging violations of HIPAA and state privacy and debt collection laws. Accretive agreed to pay $2.5 million, ceased business operations in the state, and cannot reenter Minnesota for six years without the agreement of the Attorney General.

More information on the FTC settlement is available at:
http://www.ftc.gov/news-events/press-releases/2013/12/accretive-health-settles-ftc-charges-it-failed-adequately-protect

On January 7, 2014, the U.S. Department of Health and Human Services published a Notice of Proposed Rulemaking to remove unnecessary legal barriers under the HIPAA Privacy Rule that may prevent states from reporting certain information to the National Instant Criminal

Background Check System (NICS). The NICS helps to ensure that guns are not sold to those prohibited by law from having them, such as felons, those convicted of domestic violence, and individuals involuntarily committed to a mental institution. According to HHS, the NICS is only as effective as the information that is available to it.

The proposed rule, which is part of the Obama administration's efforts to curb gun violence, permits (but does not require) states and certain covered entities to disclose to the NICS the minimum necessary identifying information about individuals who have been involuntarily committed to a mental institution or otherwise have been determined by a lawful authority to be a danger to themselves or others or to lack the mental capacity to manage their own affairs. The proposed permission focuses on those entities who perform the relevant commitments, adjudications, or data repository functions. The limited information to be reported to NICS will not include clinical, diagnostic, or other mental health information. The proposed rule would not change the existing permitted uses and disclosures of PHI under the HIPAA Privacy Rule. Comments on the proposed rule are due by March 10, 2014.

More information is available at:
http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/NICS/index.html

Reported by Elizabeth F. Hodge, Akerman, LLP

FACILITY LICENSURE

Compounding Pharmacies: Ongoing Developments

A. The Drug Quality and Security Act

With more than sixty-four confirmed deaths and seven hundred and fifty-one reported cases of fungal meningitis linked to the 2012 New England Compounding Center outbreak, the federal government has acted. Last November, President Barack Obama signed the Drug Quality and Security Act (the "Act") into law focusing additional attention on compounding pharmacies. H.R. Res 3204 113th Cong. (2013). The Act is comprised of two distinct sub-parts: (a) the Compounding Quality Act; and (b) the Drug Supply Chain Security Act.

Under the Compound Quality Act, certain compounding pharmacies are encouraged to register with the Food and Drug Administration (FDA) as an "Outsourcing Facility" and submit to: (a) enhanced labeling requirements; (b) new FDA inspection and quality requirements; (c) specific adverse event reporting requirements; and (d) additional costs, including an initial registration fee of $15,000.

Although FDA Outsourcing Facility registration with is completely voluntary, industry analysts suggest that hospitals and other providers may limit future purchases to registered entities. In a December 2013 press conference, the FDA publically encouraged healthcare providers and health networks to purchase product from FDA-registered outsourcing facilities.

B. The Florida Response

Florida regulators have progressively overhauled licensure process for compounding pharmacies in this state. Effective September 2013, Florida pharmacies that engage in the preparation of sterile compounded products must to obtain a Special Sterile Compounding Permit. See Fla. Admin. Code r. 64B16-28.100(8). The standards of practice for compounding sterile preparations may be found in Rule 64B16-27.797, Florida Administrative Code.

To obtain the new Special Sterile Compounding Permit, an applicant must (a) already hold another pharmacy permit; and (b) submit form DH-MQA 1270, 5/13, titled Sterile Compounding Pharmacy Permit Application. Therefore, if the licensee currently holds a combined Community/Special Parenteral & Enteral permit, or a combined Special Closed/Parenteral & Enteral permit, it will be required to apply for the Special Sterile Compounding Permit and maintain the two separate permits.

In addition to the new permitting requirements, the Florida Board of Pharmacy announced in December that it intends to further modify amend Florida's Administrative Rules for compounding pharmacies to address: (a) "any necessary or needed changes of a technical or substantive nature"; (b) changes necessary to conform with the recently enacted Federal CQA; and (c) changes needed in relation to the allowable quantity of compounded drugs for Office Use Compounding. Fla. Admin. Code r. 64B16-27.700. Although the scope of the proposed changes are unknown, it is very likely that additional changes will take place in 2014.

Submitted by Adam R. Maingot

Second DCA: Agency Improperly Rejected the ALJ's Recommended Order

In Bridlewood Grp. Home v. Agency for Pers. with Disabilities, 2D13-43 (Fla. 2d DCA Dec. 20, 2013), Bridlewood Group Home ("Bridlewood") appeals a final order revoking its license to operate. The Agency for Persons with Disabilities ("APD") sought revocation of Bridlewood's license after a Bridlewood employee ("Sanders") sexually battered a disabled patient at the group home in 2010.

Sections 393.0673(1)(b), 393.13(3)(a) and (3)(g), Florida Statutes (2010), and Florida Administrative Code Rules 65G-2.012(6)(a) and (15)(b), instruct: (1) persons with developmental disabilities have the right to be free from abuse, neglect, and exploitation; (2) a licensee is subject to disciplinary action if they are responsible for the abuse, neglect, or exploitation of a vulnerable adult; (3) facilities shall take reasonable precautions to protect their clients from injurious behavior; and (4) facilities shall be equipped to assure safe care and supervision for their clients. See §§ 393.0673(1)(b), 393.13(3)(a) & (3)(g); Fla. Admin. Code R. 65G-2.012(6)(a) & (15)(b).

In the administrative law judge's ("ALJ") recommended order ("RO"), the ALJ determined that APD failed to present any evidence that Bridlewood: (1) inadequately screened, trained, or supervised Saunders or (2) inappropriately took any action involving Saunders' hiring, training, or supervision. Accordingly, the ALJ held that there was no evidence that Bridlewood, the licensee, was somehow responsible for the sexual battery committed by one of its employees by way of negligent supervision or otherwise.

APD then filed exceptions to the ALJ's RO and, thereafter, adopted one of the exceptions, finding that the license revocation was warranted. See Fla. Stat. § 120.57(1)(l) (2010); see also Verleni v. Dep't of Health, Bd. of Podiatric Med., 853 So. 2d 481, 483 (Fla. 1st DCA 2003) (holding that an agency may reject the findings of fact in a RO, when the agency states with particularity that the findings are not based on competent substantial evidence).

Ultimately, the Second DCA determined that APD failed to address the ALJ's findings of fact as they related to Bridlewood's conduct leading up to the incident. Instead, the Court held that APD simply alleged that: (1) the ALJ "improperly rejected uncontroverted material facts" related to the post-incident handling of the sexual battery; (2) the "ALJ lack[ed] the expertise to determine the credibility of a witness with a developmental disability when such witness's credibility is called into question by another person with a close personal relationship with the witness"; and (3) it was APD which had "special expertise and experience" to review such situations. Citing Heifetz v. Dep't of Bus. Regulation, Div. of Alcoholic Beverages & Tobacco, the Court determined that APD failed to abide by the standard of review required when an agency reviews an ALJ's RO. See 475 So. 2d 1277, 1281 (Fla. 1st DCA 1985) ("An "agency may not reject the [ALJ's] findings unless there is no competent, substantial evidence from which the finding could reasonably be inferred. The agency is not authorized to weigh the evidence presented, judge credibility of witnesses, or otherwise interpret the evidence to fit its desired ultimate conclusion.") (internal citations omitted). The case was reversed and remanded with instructions.

Submitted by Adam R. Maingot

PROFESSIONAL LICENSURE

Third DCA Reverses Scrivener's Error and Affirms Department of Medicine Final Order.

The Department of Health ("Department") filed an administrative complaint against Dr. Castellon, a licensed medical doctor, alleging that: (1) a 35 cm x 35 cm surgical sponge was left in a patient operated on by Dr. Castellon; (2) the sponge was readily palpable; and (3) a subsequent operative procedure was necessary to remove the sponge. Section 456.072(1)(cc), Florida Statutes (2012), subjects a physician to discipline for leaving a foreign body in a patient. See Castellon v. Dep't. of Health, Bd. of Medicine, 3D13-642 (Fla. 3d DCA Jan. 22, 2014).

Dr. Castellon elected an informal hearing under section 120.57(2), Florida Statutes (2012) and did not dispute the findings of fact. During the hearing, Dr. Castellon established the following mitigating facts: (1) a forty-year record devoid of disciplinary actions; (2) the complete recovery by the patient; and (3) that three assistants (one of them a surgeon licensed in Nicaragua, but not

yet licensed in Florida) had confirmed through four sponge counts that all sponges had been removed before Dr. Castellon began to close the incision site.

Despite Dr. Castellon's reliance argument, all ten panel members voted to enter the findings in the Department's final order regarding the enumerated act and the discipline to be imposed. See Abram v. Dep't. of Health, Bd. of Medicine, 13 So. 3d 85 (Fla. 4th DCA 2009) (determining that findings related to a non-strict liability statute are expressly permissive rather than mandatory). Pursuant to section 456.072(2)(d), Florida Statutes (2012), the Board may impose an administrative fine of up to $10,000 for each occurrence of 456.072(1)(cc). Ultimately, the Board's final order imposed costs (not fines) in the amount of $5,000.00.

Upon review, the Third DCA determined that the final order's imposition of costs (rather than a fine) was a mere scrivener's error, and that because (1) Dr. Castellon did not dispute the facts sufficient to establish a prima facie violation of section 456.072(1)(cc); and (2) that the panel unanimously voted to impose a penalty pursuant to section 456.072(2)(d), that the Third DCA would affirm the panel's findings and conclusions. The Court specifically noted that it found no misinterpretation of law, no procedural error, and no abuse of discretion.

Submitted by Adam R. Maingot