Dear Health Law Section Members:

The Florida Bar Health Law Section ("HLS") website has been updated with January – March 2022 articles on significant developments in the health law arena that may be of interest to you in your practice.

These summaries are presented to HLS members for general information only and do not constitute legal advice from the Florida Bar or the HLS. HLS thanks the following volunteers who have generously donated their time to prepare these summaries for our members:

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REGULATORY AND LEGISLATIVE UPDATES

Florida Continues Pursuit Of Improved Patient Safety

Florida is continuing its efforts to improve patient safety in hospitals and ambulatory surgical centers (ASCs). The Florida Legislature approved a requirement that hospitals and ambulatory surgical centers (ASCs) conduct patient safety surveys and tasked the Agency for Health Care Administration (AHCA) with implementing a rule specifying the submission process for these surveys. AHCA's proposed rule (Proposed Rule) was announced on November 4, 2021.

Patient Safety Surveys

Every two years, Florida licensed hospitals and ASCs must conduct a patient safety culture survey using the Survey on Patient Safety Culture developed by the federal Agency for Healthcare Research and Quality (AHRQ) (the Safety Statute). The surveys must be conducted anonymously to encourage completion of the surveys by all employed and contracted staff. The facilities may contract with vendors to administer the survey.

The survey data must be submitted to AHCA in the format specified by the Proposed Rule once it has been finalized and implemented. The submissions must include the survey's participation rate, although no minimum amount of participation is specified. AHCA's Proposed Rule outlines the requirements described below.

Reporting Period

Within twenty-four months of the Proposed Rule becoming effective, and for each subsequent licensure renewal, each hospital and each ASC will have to submit patient safety culture survey data to AHCA.

Data File Specifications

The facilities must submit the data to AHCA in the format specified by AHRQ. AHRQ has different data file specifications for hospitals and ASCs.

Survey Questions

AHCA will provide the survey questions to be asked, which are different for ASCs and hospitals. While the general concepts are similar, the categories of the questions are different. Most questions in both surveys require the participant to respond to statements by answering: Never; Rarely; Sometimes; Most of the time; Always; Does not apply or do not know.

The Hospital Survey groups the questions into specific sections: (1) the participant's work area, (2) management at the hospital, (3) communication, (4) the reporting of patient safety events, (5) patient safety rating, (6) the hospital, and (7) care provided.

The ASC Survey groups the questions into these sections: (1) working environment, (2) teamwork and training, (3) organizational learning, (4) documentation of near misses, (5) management

support for patient safety, (6) overall facility rating, and (7) communication in the surgery/procedure room.

Additional Patient Safety Requirements

Hospitals and ASCs need not submit patient safety surveys yet, as the Proposed Rule requires the surveys to be conducted within twenty-four months of the Proposed Rule's effective date. However, the requirement that surveys be conducted is only a portion of Florida's strategy for achieving patient safety.

The Safety Statute requires that hospitals and ASCs already have the following in place:

- The adoption of a patient safety plan. The plan will be deemed to comply with this requirement if it adheres to the Centers for Medicare & Medicaid Services' conditions of participation for quality assessments and performance improvement plans.
- Appointment of a patient safety officer and a committee to promote the health and safety of patients, review the quality of patient safety measures, and assist in implementing the facility's patient safety plan. The committee must include at least one person who is not employed or practicing in the facility.

Besides the above requirements, hospitals must provide AHCA's Hospital Quality Measures/Patient Safety Information Form (1) to any patient or patient's representative upon scheduling the patient's nonemergency care, or (2) to any other stabilized patient or patient's representative within 24 hours of the patient being stabilized or at the time of discharge, whichever comes first. In addition, the form must always be provided to any person who requests this information. The form must include the hospital and statewide average for the most recent year related to these quality measures:

- The rate of hospital-acquired infections;
- The overall rating of the Hospital Consumer Assessment of Healthcare Providers and Systems survey; and
- The 15-day readmission rate.

Prepare Plan for Patient Safety

Florida is making progress in its goal of advancing patient safety. Hospitals and ASCs are out of compliance if they are not adhering to the implemented patient safety requirements, such as the adoption of a patient safety plan. As soon as the Proposed Rule for patient surveys is finalized, hospitals and ASCs will need to turn their attention to implementing a process for timely submission of the biennial surveys.

Submitted by: Kirk S. Davis, Esq. & Danielle C. Gordet, Akerman

No Surprises Act: Good Faith Estimate Requirements

The No Surprises Act (NSA) imposes numerous requirements on health care facilities and other providers regarding protections against surprise billings. The requirements include posting and delivering notices regarding the consumer protections of the NSA, providing good-faith estimates (GFE) of services and procedures, and limitations on billing for those services under certain circumstances. This alert addresses only the GFE requirements. While much of the NSA applies only to certain facilities, such as hospitals and surgery centers, the GFE requirements have a much broader application to include physician practices. These requirements were effective January 1, 2022, and those health care providers subject to the NSA, must act immediately to comply with the NSA

The NSA requires providers to provide a notice of certain of the NSA consumer protections and a GFE of the expected charges (including any discounts) for items or services to self-pay patients. Additionally, the provider must provide a GFE to a self-pay patient merely shopping for items or services—prior to scheduling any services.

Who are "self-pay patients?"

"Self-pay patients" are those who do not have health care coverage from a health insurance issuer nor receive benefits from a governmental health benefit plan. The definition of self-pay patients also includes, however, insured patients who choose not to use their benefits for a particular service or item. Also, if a patient has coverage that does not provide for out of network coverage, the individual is considered "self-pay" as to the out of network provider. A patient is, however, an insured individual if the coverage includes out of network coverage, albeit with higher deductibles or copays (unless they choose not to use the coverage). Practically speaking, the health care provider now must inquire and determine the patient's status as insured or self-pay—including whether the patient wishes not to use any health care coverage or benefit.

What Items or services are subject to the NSA?

The GFE must be provided regarding any service or item provided by the provider. This includes physician services, testing, durable medical equipment, therapy, such as physical therapy or infusion services, and procedures. For example, if an individual with no insurance or governmental health benefit calls a physician practice to schedule an appointment, the GFE requirements are triggered. Typically, these requirements are triggered only for services provided by the provider and not by another provider. For example, if the self-pay patient calls a physician practice to inquire about the cost of an imaging test ordered by the doctor, but to be provided and scheduled by an independent diagnostic facility, the health care provider does not must provide a GFE for the imaging study.

What health care providers are subject to the GFE requirements of the NSA?

Providers of health care services are broadly defined as physicians or other health care providers acting within the scope of their state licenses, along with institutions, such as hospitals, surgery centers, laboratories, federally qualified health care centers, and diagnostic testing facilities – any facility requiring a state license to provide services must comply with the GFE requirements.

"Convening providers" must provide the notice and the GFEs. A "convening provider" is one responsible for scheduling the primary service or item or who receives a request from an individual shopping for health care items or services provided by that provider and other providers who provide services related to the primary service. If a self-pay patient calls a physician practice to inquire about the cost of a procedure at a surgery center to be performed by a physician in the practice, the physician practice is the convening provider. The convening provider and the surgery center are considered "co-providers" and will need to coordinate the provision of the GFE, as described below.

What notice must be provided?

The provider must give both oral and written information. When a self-pay patient calls regarding the cost or availability of a health care service or item, or to schedule a service or item, the provider must tell the self-pay patient he may obtain a GFE. The provider must display a notice about the availability of the GFE in the office where scheduling occurs and on the website of the provider. The Center for Medicare & Medicaid Services (CMS) has provided a model notice, available at https://www.cms.gov/regulations-and-guidancelegislationpaperworkreductionactof1995pra-listing/cms-10791. In addition, the provider must provide a GFE. The GFE must be provided in paper format or electronically according to the patient's wishes, even if the patient requests the estimate orally. The notice must be provided in easily understandable format and in languages spoken by the self-pay patients. The self-pay patient must be able to save and print the GFE.

What must the GFE include?

CMS has provided a model form to be used by providers, available at the link above. CMS does not mandate use of the form, but if a provider in good faith uses the model form, it will be deemed in compliance with the NSA. The GFE must include the patient's name and date of birth, a description of the primary item or service, a list of other items or services reasonably expected to be provided with the primary item or service, diagnostic and expected service codes, expected charges, the name and National Provider Identifier (NPI) number of the provider, the state and location of the place where services are to be provided, a description of items or services that the provider believes may require separate scheduling, either before or after the primary services (e.g., lab work before surgery), and a statement that a GFE estimate of such additional services would be provided upon scheduling or request. The GFE must include certain disclaimers to include there may be additional items or service not included in the GFE, that the GFE is only an estimate based on what is reasonably expected during the service, and that the charges could differ. The provider must also notify the patient of a dispute resolution process if the expected charges are substantially over the estimate. The provider must inform the self-pay patient that the GFE is not a contract and that the patient does not have to obtain the services from the provider.

When must the GFE be provided?

If a patient requests a GFE for an item or service and is not yet attempting to schedule the item or service, the provider must furnish the GFE within three business days of the request.

If the primary item or service is scheduled for less than three business days from the scheduling, no GFE is required.

If the primary item or service is scheduled between three and nine days after the scheduling, the provider must furnish the GFE within one business day of the scheduling.

If the primary item or service is scheduled 10 days or more after the scheduling, the provider must furnish the GFE within three days after the date the primary item or service is scheduled.

What if the patient requires multiple visits or services?

The provider may issue a GFE for recurring primary items or services for up to 12 months. The GFE must explain the frequency, the time frame, and the total of expected recurrences. The providers must issue a new GFE at the end of the 12 months.

How must changes or updates be provided?

If the information in a GFE needs to be updated or changed, the convening provider must notify self-pay patient of the change or update no less than one day before the scheduled service or item. Regarding a GFE provided to a self-pay patient merely shopping for services, the updated GFE should be provided in the time frames stated above if the patient then schedules the services.

What are the requirements for co-providers?

CMS recognizes that the coordination efforts required of co-providers are complex and may require additional time for the co-providers to create processes and procedures to ensure compliance. Thus, CMS will exercise its enforcement discretion for the fiscal year 2022 regarding these requirements. Co-providers must coordinate their efforts to provide the GFE to patients. For example, when a physician practice is scheduling a procedure at a surgery center, both providers must provide a GFE to the self-pay patients, and the convening provider must coordinate the provision of the GFE. Within one business day of receiving a request for a GFE or scheduling an item or service, the convening provider must contact all co-providers who are reasonably expected to provide a service with the primary item or service. The convening provider must inform the co-providers of the obligation to respond with the following information within one day of the request: patient's name and date of birth, a list of items or services reasonably expected to be provided by the co- provider, diagnosis and expected service codes, expected charges, the name and NPI number of the provider, state and location of services, and a disclaimer that the GFE is not a contract and that the patient does not have to obtain the services from the co-provider. Changes and updated information must be provided to a convening provider. If there is any change in the co-providers less than one day before the service is scheduled, the replacement co-provider must accept the expected charges in the GFE by the original co-provider.

What are the consequences of noncompliance?

CMS may impose a penalty of up to $10,000 per violation. If the actual billed charges exceed the estimate by $400 or more, the self-pay patient may dispute resolution process defined in the regulations. If it is determined that the provider should have known of the inaccuracy, the charges will be adjusted.

Submitted by: Grant Dearborn, Esq. & Lisa Thomas, Esq., Shumaker

Federal Regulatory – Food and Drug Administration

Proposed FDA Rules Could Be Game Changers for the Pharmaceutical Supply Chain

New federal regulations have been proposed that will affect licensure of wholesale drug distributors and third-party logistics providers (3PLs). The Drug Supply Chain Security Act became law in 2013. The U.S. Food and Drug Administration (FDA) published proposed rules on Feb. 4, 2022, that would preempt state and local licensure requirements for many companies in the drug supply chain. Members of the public may submit written comments regarding the proposal. The deadline to provide comments is June 6, 2022.

The FDA recognizes that "[a] breach at any point in the supply chain carries potential for dangerous, and even deadly, outcomes for American consumers." In the preamble to the proposed rules, the FDA stated that "[t]heft and diversion of prescription drugs continue to be major issues contributing to drug shortages and creating significant financial losses, the effects of which cascade through the supply chain to consumers." The rules are designed to "secure and strengthen the supply chain." All 3PLs and wholesale distributors will be held to national standards relating to handling, storage and transportation of prescription drugs, instead of the current "patchwork" of differing standards among the states. States with their own licensure programs will continue to issue permits. If a state lacks a licensing program that complies with the federal rules, the "FDA will be the licensing authority."

The proposed rules, if finalized in their current form, could have a substantial effect on retail pharmacies selling into the wholesale market. The proposal addresses the FDA's policy to allow pharmacies to sell drugs to licensed practitioners for office use without those transactions being considered wholesale distribution. Any sales to a wholesale distributor, or sales above 5 percent for office use by healthcare providers, would require the pharmacy to obtain a wholesale distributor permit, as would any sales to other pharmacies except as required to fulfill a specific patient need.

The proposed rules would impose other regulatory requirements in a number of areas, including:

- defining 3PL activities
- describing events that would constitute a change of ownership
- defining a "designated representative," which raises questions about whether specific state requirements for designated representatives would continue, such as Florida's requirement that such individuals pass a written, state-required exam
- carving out a corporate office or headquarters from the definition of "facility" if the location does not store or handle drugs and only provides oversight, support or business administrative functions. Clarification may be needed to make it clear whether sales locations, such as call centers, require a permit. The regulatory preamble indicates that entities that do not take physical possession of drugs (such as a broker) may still be engaged in activities that meet the definition of a wholesale distributor or manufacturer
- requiring entities in the supply chain to authenticate products suspected to be illegitimate, and to do business only with licensed, authorized trading partners

- imposing an obligation on 3PLs and wholesale distributors to report any changes in information submitted on the licensure application to be reported within 30 calendar days of the change
- requiring all 3PLs with existing state licenses to obtain new licenses in accordance with the federal standards
- imposing good storage practices requirements
- imposing certain background screening and other requirements for personnel
- mandating written policies and procedures on numerous topics regarding operating the 3PL or pharmaceutical wholesaler's business
- providing for only 10 days after a permit is denied to request a hearing
- requiring surety bonds
- requiring a satisfactory inspection prior to licensure and routinely thereafter at least once every three years
- requiring certain annual reporting to the FDA

The FDA has determined that the "Federal requirements will establish both a 'floor' and a 'ceiling'" for wholesale distributors and 3PLs. In other words, states cannot impose requirements that differ from the federal standards. This could mean substantial regulatory changes for companies that operate in states, such as Florida, that impose more stringent requirements. Such state requirements will be preempted only once the rules are finalized and become effective. Because the final rules could have a dramatic impact on the way wholesalers and 3PLs do business, companies should consider submitting comments regarding how the regulations may affect their operations. All members of the pharmaceutical supply chain should be aware that changes are on the horizon.

Submitted by: **Shannon Britton Hartsfield, Esq., Holland & Knight**