January 2024

Dear Health Law Section Members:

The Health Law Section ("HLS") website has been updated with Fall 2023 articles on significant developments in health law 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 its Health Law Section. HLS thanks these volunteers who have generously donated their time to prepare these summaries for our members.

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ADMINISTRATIVE LAW [DEA, FDA, HHS]

THE NO SURPRISES ACT: Hoping for an End to the Surprises

By looking at the events that have transpired since the Consolidated Appropriations Act, 2021, which includes the No Surprises Act (the Act), was signed into law, it is clear that the Departments of Health and Human Services, Labor, and Treasury (collectively, the Departments) have lost their way. The United States District Court for the Eastern District of Texas (the Texas court) has consistently agreed with providers and ruled against the Departments because they have repeatedly violated the Administrative Procedure Act (APA) and disregarded the original intent of the Act: to protect consumers from surprise medical bills and to streamline disputes between payors and providers through an independent dispute resolution process (IDR).

For example, in February 2022, the Texas court invalidated the portion of the Federal IDR process that hampered out-of-network providers' efforts to negotiate payment rates by essentially creating a rebuttable presumption in favor of the insurer's median contracted rate for the service, the QPA. The same court invalidated a similar regulation that applied to air ambulance payment disputes in July 2022. The Texas court again invalidated challenged provisions of rules implementing the Act because they improperly permitted the QPA to favor insurers and lowered payments to out-of-network providers in February 2023. That same court found that the Departments' increased IDR administrative fee, from $50 to $350, violated the Administrative Procedures Act by failing to provide a notice and comment period on August 3, 2023. Most recently, on August 24, 2023, the Texas court set aside portions of the Departments' implementing regulations because all but one of the challenged regulations regarding the QPA calculation violated the Act's plain text.

Given this consistent string of judicial losses, where do the Act's regulations go from here? The Departments need to go back to the basics of the Act's purpose by issuing interpretations and guidance that follow the Act's text and basic principles. Ironically, the Departments' rulemaking to date has devolved into litigation between providers and payors, which is the same problem that has infested our healthcare system for decades and that the Act was partly intended to avoid.

It is inadequate to repeat the phrase "our healthcare system is complicated." It should not take multiple lawsuits interpreting the Act sentence by clause by paragraph to determine the Act's purpose. Such litigation leads to a breakdown of the system, and none of the three major players benefit. The patients, the providers, and the payors all should be working together to put a system in place that functions for everyone and not to the detriment of anyone. Again, we must remember that patients — not profits — are at the forefront of the Act. Yet the arguments that continue to be presented before the courts are that the rules being implemented favor payors over providers, with no mention of the patients. The American Hospital Association has said that the rules being issued by the Departments "unfairly favor insurers to the detriment of hospitals and physicians who actually care for patients. These consumer protections need to be implemented in the right way, and this misses the mark."

Consequently, the Departments suspended the majority of Federal IDR disputes following the Texas court's August 24, 2023, Order. On September 21, 2023, the Centers for Medicare & Medicaid Services (CMS) posted a new notice on its website:

Effective September 21, 2023, the Departments have directed certified IDR entities to resume processing all single and bundled disputes *already submitted to the IDR portal and assigned to a certified IDR entity*. **The ability to initiate new disputes involving air ambulance items or services as well as batched disputes for air ambulance and non-air ambulance items and services is currently unavailable. IDR portal functionalities related to previously initiated batched disputes are also unavailable.** Disputing parties should continue to engage in open negotiation according to the required timeframes. (emphasis added.)

While there are No Surprises in what has transpired, the Departments should use the suspension to cure several issues with how they are attempting to implement the Act.

At the very least, it is clear that unless the Departments make substantial changes to the Federal IDR process, litigation will continue. If the Texas court's past decisions are any indication of future rulings, providers likely will continue to be successful. As the Texas Medical Association (TMA) recently posted on their website, "Despite TMA's continued success in its No Surprises Act litigation, the battle for a fair IDR process is still far from over." (emphasis added.) If the Departments have any hope of avoiding more litigation, any rules and other guidance they issue next will need to stay as close to the original intent and language of the Act as possible. This includes ensuring that the determination of the QPA constitutes a fair approach that does not leave any room for speculation that it is tilted to favor anyone.

Another important step for the Departments will be to ensure that they give a notice and comment period for any rules that require one. The APA requires that agencies provide a "notice-and-comment" procedure that allows the public to submit comments to the Departments regarding proposed substantive rules unless an exception applies. The Texas court, for example, found that the substantial increase in the Federal IDR administrative fee violated the APA because no notice and comment period was provided. Given the Texas court's history of ruling against the Departments, the agencies would be wise to issue a notice and comment period whenever required. Perhaps the Departments are starting to catch on, because on September 20, 2023, they released a proposed rule (finally giving an opportunity for notice and comment!) that would set the Federal IDR administrative fee at $150 per party per dispute for disputes initiated on or after the effective date of the rule or January 1, 2024 — whichever comes later. Providers and anyone else who wishes to submit their comments on this proposed rule must do so no later than 30 days after the proposed rule is published in the Federal Register, which is scheduled for September 26, 2023.

While providers are likely happy with their string of recent wins from the Texas court, it is not all good news for them. No new disputes or previously initiated batched disputes will be reviewed during the current suspension. This pause in the process could be financially problematic for providers waiting for decisions regarding their payment disputes. Moreover, the ongoing open negotiations mean there will continue to be a build-up of disputes waiting for arbitration, creating a definite backlog when the process resumes.

The Act had a simple premise. Figuring out how to implement it has been a procedural nightmare. The Departments must go back to the basics and do what is in the best interest of all parties, but,

most importantly, assure that the patients receive the quality healthcare that our system is designed to provide them.

October 6, 2023, Update: The Centers for Medicare & Medicaid Services (CMS) posted a new notice on its website, notifying the public that the Federal Independent Dispute Resolution (IDR) Portal is re-opened, effective October 6, 2023, to initiate certain single and bundled disputes. Processing of in-progress batched disputes, new batched disputes, and new air ambulance disputes remains temporarily suspended while the Departments update batching and air ambulance guidance and operations to align with the Texas Court's recent opinions and orders. Please refer to the CMS notice for information regarding additional time that the Departments are providing parties to submit and respond to certain new disputes.

Link to original post: https://www.akerman.com/en/perspectives/hrx-the-no-surprises-act-hoping-for-an-end-to-the-surprises.html

Submitted by Marcy Hahn-Saperstein, Esq., FL HLS Executive Council member for authors Kirk S. Davis, Esq., and Danielle C. Gordet, Esq., Akerman

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DEA Issues Second Temporary Rule Extending Controlled Substance Prescribing Flexibilities Through December 2024

On October 6, 2023, the Drug Enforcement Agency (DEA) and the Department of Health and Human Services (HHS) issued a Second Temporary Rule further extending the ability to prescribe controlled substance via telemedicine through the end of 2024.

Key Takeaways

On November 11, 2023, the Second Temporary Rule takes effect and extends the COVID-19 Public Health Emergency (PHE) telemedicine-controlled substance prescribing flexibilities through December 31, 2024.

The Second Temporary Rule removes the "grace period" established by the previous temporary rule. Instead, it extends telemedicine prescribing flexibilities to all practitioner-patient relationships regardless of when the relationship was established, thereby removing the distinction between new and established telemedicine patients. Under the first temporary rule, only practitioner-patient relationships established prior to November 11, 2023, were granted telemedicine flexibilities for an additional year.

It is unclear whether the DEA will create a special registration process, which it declined to do through past proposed rules. The special registration process was a key topic at the recent DEA telemedicine listening sessions, which followed DEA's prior comments set forth in the DEA's

listening sessions notice. In that notice, the DEA stated they are "open to considering – for some controlled substances" a special registry without in-person requirements, although additional prescribing data collection requirements to prevent diversion would likely be included.

The DEA continues to review both the 38,000+ comments it received in response to its two February 2023 proposed rules, and the comments and presentations received during the recent DEA telemedicine listening sessions. Further stakeholder commentary may be forthcoming, as DEA announced its intention during the listening sessions to allow an additional comment period regarding its proposed rules.

As a result of the PHE, the DEA granted temporary exceptions to the Ryan Haight Act and the DEA's implementing regulations under 21 U.S.C. 802(54)(D), allowing the prescribing of controlled substances via telemedicine absent an in-person medical evaluation of the patient.

These flexibilities authorize practitioners to prescribe schedule II-V controlled substances via audio-video telemedicine encounter. Additionally, practitioners may prescribe schedule III-V narcotic-controlled medications approved by the Food and Drug Administration (FDA) for maintenance and withdrawal management treatment of opioid use disorder via audio-only telemedicine encounters, without requiring an in-person medical evaluation. The DEA extended the "full set" of telemedicine prescribing flexibilities through an initial temporary rule issued on May 10, 2023. The initial temporary rule allows for the prescribing of controlled substances for new patients, absent an initial in-person evaluation, through November 11, 2023; and provides an additional one-year grace period for established telemedicine patients through November 11, 2024. The Second Temporary Rule extends PHE flexibilities through December 31, 2024, for all patients regardless of when the practitioner-patient relationship is established.

The Second Temporary Rule follows a series of telemedicine listening sessions, which the DEA hosted on September 12th and 13th in response to wide-spread criticism of its release of two Notices of Proposed Rulemaking (the "proposed rules") in February 2023. The proposed rules stated an intention to reinstate strict limitations on the virtual prescribing of controlled substances and signaled a significant roll back of the in-person medical evaluation flexibilities extended during the PHE. In response, most listening session presenters offered comments in four categories of concern: 1) the telemedicine controlled substance prescribing in-person visit requirement, 2) the proposed thirty-day prescribing limit, 3) proposed reporting requirements (e.g., notating on prescriptions that they were prescribed via telemedicine), and 4) the potential for a telemedicine prescribing special registration process. Provider-specific issues also appeared, including an emphasis on exceptions to DEA requirements applicable to specialized care services like palliative and end-of-life providers. Stakeholder consensus highlighted the industry's desire for a permanent extension of prescribing flexibilities to support patient access to necessary medications without the perceived arbitrary in-person visit requirement.

DEA leadership approached the listening sessions as fact gathering sessions, providing little to no commentary other than to clarify questions. The DEA Administrator Anne Milgram asked questions regarding how the DEA can better use data that providers, pharmacies, and insurers are required to track, maintain, and report. DEA Deputy Assistant Administrator Tom Prevoznik also

asked several pointed questions regarding patient identity verification procedures, potentially signaling DEA interest in ensuring accurate address verification of telemedicine patients.

Many stakeholders expressed interest in the creation of a special registration process for remote prescribing, which the 15-year old Ryan Haight Act mandates. Under the Ryan Haight Act, the DEA is required to establish a special registration process for the prescribing of controlled substances via telemedicine. Congress registered its support for the special registration process by delivering a letter addressed to DEA Administrator Anne Milgram on September 13 stating, "[Congress] created a 'special registration' exception, not as an option for DEA to utilize but a requirement to do so" acknowledging that DEA's most recent proposed rules did not meet that obligation. The letter emphasized the potential for a special registration process to balance the need for provider clinical judgement and flexibility in prescribing appropriateness via telemedicine encounters.

During the listening sessions, DEA Administrator Anne Milgram indicated that a forthcoming comment period will take place in the fall of 2023, which will allow for additional written comments before any rules become final. DEA has indicated that it anticipates implementing a final set of regulations related to controlled substance prescribing via telemedicine by the fall of 2024. While the Second Temporary Rule provides additional flexibility for telemedicine companies and practitioners to continue prescribing to patients absent an in-person medical evaluation, it remains unclear whether the DEA will propose to implement similar flexibilities in 2024 on a permanent basis.

Link to original post: https://www.polsinelli.com/publications/dea-issues-second-temporary-rule-extending-controlled-substance-prescribing-flexibilities-through-december-2024

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STATE LEGISLATION

Board of Nursing Issues Declaratory Statement Regarding Botox Injections by RNs

The Scope of Practice for a Registered Nurse isn't always clear. The Florida Nurse Practice Act (Florida Statute Ch. § 464) and the Rules of the Florida Board of Nursing (Florida Administrative Codes, Title 64B9) exist to establish regulations, authority, and guidance regarding the practice of nursing. The issue of whether a registered nurse can legally administer Botox has been clearly addressed under Florida law. Previous rulings set a precedent when a nurse was disciplined for performing Botox injections on a client without a physician's direct orders (Department of Health v. Trisha Lorraine White, R.N. Case Number 2016-13884). However, this ruling seemed to leave more questions than answers. The ruling did not clearly state whether a nurse is allowed to perform

Botox injections if acting pursuant to a physician's orders. In *White*, the court held that even pursuant to a physician's orders a registered nurse does not possess the requisite educational preparation to perform the procedure and that doing so would be practicing beyond the scope of a nursing license. Without clarification, this matter left unanswered questions for nurses, med spas, and clinics who could potentially benefit from having nurses perform Botox procedures.

Board of Nursing Issues Declaratory Statement Regarding Botox Injections by RNs

Per the Board of Nursing, if a specific act is questionable, a declaratory statement may be requested to provide clarity. The Board of Nursing defines a **declaratory statement** as a means for resolving a controversy or answering questions or doubts concerning the applicability of statutory provisions, rules, or orders over which the board, or department when there is no board. On September 26, 2022, Jessica James, a registered nurse (R.N.) from Pensacola, Florida requested a declaratory statement on clarification for the task delegation of Botox Cosmetic.

The case referenced Florida Statute § 464.003, specifically quoting, "The administration of medications and treatments as prescribed or authorized by a duly licensed practitioner authorized by the laws of this state to prescribe such medications and treatments." Jessica James' request went on to identify some prerequisites in her case for Botox task delegation eligibility by stating that the physician would first examine the patient and write an order detailing the specific muscles to be injected as well as the units per injection site before delegating the task to a registered nurse.

The Board of Nursing concluded that it is within the scope of practice for this particular case to allow the task delegation of administering of Botox. It should be noted that the Board of Nursing mentioned the "Petitioner's specific and particular education, training, and experience" when making this decision. In this particular case, Jessica James, stated that she had experience in this field because she had observed aesthetic injections for 4 years and had completed Method Aesthetics Academy Level I training.

This finding opens the door to the possibility for other qualified nurses to administer Botox under the supervision of a physician with the appropriate trainings and education. At the very least, this finding displays more progressive thought than previous rulings and statements that disallowed nurses to partake and assist in Botox injections. While this matter remains open-ended and subject to specific conditions, it most definitely provides some transparency for those concerned.

Link to original article and podcast:https://www.joneshealthlaw.com/board-of-nursing-issues-declaratory-statement-regarding-botox-injections-by-rns/

Submitted by Jamaal R. Jones, Esq., Jones Health Law

ACTION REQUIRED TO AVOID FINES! DEADLINE APPROACHING:

Florida Pharmacy Benefit Managers Must Be Licensed as a Third-Party Administrator by January 1, 2024

Pharmacy Benefit Managers (PBMs) take note! Under Florida's new Prescription Drug Reform Act, PBMs must be licensed as an insurance administrator (also known as a third-party administrator, or TPA). Under this new law, any entity that wishes to provide PBM services after January 1, 2024, must be licensed as a TPA.

The Florida Office of Insurance Regulation (OIR) has adopted a new TPA license application that incorporates the additional licensing requirements for PBMs. The TPA license application is available here. For an entity that is not currently registered as a PBM, that entity will, in addition to obtaining a TPA license, have to register as a PBM. The PBM registration form is available here.

Based on informal conversations with the OIR, we understand that many of the currently registered PBMs have not submitted their TPA license applications. The TPA licensing process can take several months, especially if a significant number of applications are submitted at or around the same time. We strongly encourage existing PBMs that wish to continue providing PBM services after January 1, 2024, to submit the TPA licensing application materials as soon as possible because the Act includes significant penalties and public scrutiny for unlicensed activities. *See* § 626.8805(1), Florida Statutes:

A person who, on or after January 1, 2024, does not hold a certificate of authority to act as an administrator while operating as a pharmacy benefit manager is subject to a fine of $10,000 per violation per day (*emphasis added)*. By January 15, 2024, the [OIR] shall submit to the Governor, the President of the Senate, and the Speaker of the House of Representatives a report detailing whether each pharmacy benefit manager operating in this state on January 1, 2024, obtained a certificate of authority on or before that date as required by this section.

Link to original post: https://www.akerman.com/en/perspectives/hrx-action-required-to-avoid-fines-deadline-approaching-florida-pharmacy-benefit-managers-must-be-licensed-as-a-third-party-administrator-by-january-1-2024.html

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