December 2016

Morris James LLP

Delaware Healthcare Industry Update

Recent Legislation: Billing

Out-of-Network Notification (HB 439)

House Bill 439, sponsored by Representative Bryon Short and Senator Patricia Blevins, addresses the situation of "surprise" bills. That is, the situation when a patient seeks and receives care, and is unaware that the provider, either in whole or in part (such as lab work and anesthesia) is out of the patient's insurance network, until the patient receives the bill. A draft of HB 439 aggressively pushed against the practice by implementing a fee schedule for all out-of-network services based on Workers' Compensation. But after feedback from clinicians and facilities that cited a lack of data at their disposal to implement the suggested changes, the legislation passed by the General Assembly took the tack of notification instead.

Under the new law, a clinician, practice, or facility may not bill an out-of-network patient more than what their insurance will cover unless the patient was notified in writing that such a bill may occur. On-the-ground implementation challenges may occur here from both the providers as they work through the paperwork and from patients who will continue to struggle to learn how far their health insurance, especially insurance obtained from the marketplace, will really take them. Interestingly, although the law does not come into effect until January 2017, in September of 2016 insurer UnitedHealthcare (UHC) changed its contract such that physician practices now must get all UHC patients to sign a provided form which states that the insured understands that they were informed to take their lab and pathology scripts to an in-network lab to be fulfilled. If patients subsequently take their scripts out-of-network, UHC reclaims the practice's E/M payment unless the practice can appeal and provide the signed form.

Practice Challenges: Parking

The Morris James Team succeeded in gaining approval for expansion of an orthopedic practice's parking lot. This may not sound like open heart surgery (wrong specialty?), but having patients with mobility issues parking off-site or long distances away presents health, safety and welfare problems and undermines the marketability of a practice. The New Castle County Board of Adjustment praised the application so here is our RX for success:

• Get started. If an engineer or surveyor tells your practice manager there is no room to add more parking or improve circulation and aesthetics, get a second opinion from a lawyer who specializes in land use law. Relief from restrictive codes may be available.

• Understand the risks. Land use applications are capital investments supporting future business, including preventing loss of patients to practices with better parking, and avoidance of possible relocation costs to address problems. But talk to your lawyer about how much discretion the local zoning authority has to deny the application, and his or her experience with regard to similar applications.

• Invest in good experts and application materials. Not all applications will be allowed under current law. As long as they are correctly presented, the zoning authority should approve them. But, if the board or other zoning authority has discretion to grant or deny an application based on subjective factors, the application materials and verbal presentation need to meet all technical requirements and tell a compelling, comprehensible story as to why relief from code requirements is warranted. At a high level, the story might go like this: "This surgi-center's parking complies with current codes as to parking, but patients constantly have to park on grass and next door. Some of them cannot walk well. With minor reconfiguration of paving, the practice can pick up 24 new spaces to alleviate the problem, but the waivers of code requirements we request are needed." Erudition matters at the end phase, technical expertise more at the beginning phase.

• Choose competent counsel. Morris James Partner Kim Hoffman, Esq. has written here about choosing a competent real estate transactions lawyer. Most of the same principles that apply to choosing a real estate transactions lawyer apply to choosing a zoning lawyer. First, if the application will be presented to a Delaware zoning board of any kind, only a lawyer may represent an applicant. Engineers, planners, and architects do not qualify, except as experts. Also, be sure the lawyer has experience before the relevant board. Zoning is local. Hire local knowledge.

• Preserve the history. Keep records of granted variances with the practice's real property records and consider recording them in the public records. Variances increase the value of land and the practice. Remember they exist when selling, refinancing, or pursuing expansion plans.

In sum, a medical practice, nursing home, hospital, or surgi-center may not need to suffer from a parking shortage. Consult a land use attorney about your options, or at least let the Morris James Zoning team regale you with some relevant war stories.

Regulatory Changes: Telemedicine/Optometry

Opiate Regulations Imminent

On October 19th, Attorney General Matt Denn held a press conference in which he highlighted his office's efforts, past and future, to combat the drug abuse epidemic. While heroin and fentanyl were front and center, prescription opiates were also implicated. This was the latest in a string of government efforts to curb overdose deaths which, according to the Delaware Division of Forensic Science, continue to rise, and even quadrupled in the case of Fentanyl-related deaths.

Laws, regulations, and new programs have deployed a range of tactics to combat drug addiction over the last three years. These include patient-facing policy changes such as Good Samaritan overdose reporting law (SB 116) and Naloxone access (HB 388); law enforcement-lead treatment options like Dover's Angel Program and New Castle County's Hero Help Program, both of which encourage addicts to come to the police to seek treatment; Public Health resources such as www.helpisherede.com; stronger penalties for drug dealers who deal fentanyl (HB 239), which has spiked in use in Delaware; Task Forces convened, such as the Prescription Drug Action Committee and, recently, the Drug Overdose Fatality Review Commission; and limitations on physician opiate dispensing and use of the Prescription Monitoring Program.

Draft regulations have been published and republished, with final publication expected by the end of the year, which take a wider scope by encompassing not only physicians, but all prescribers. They seek to limit the amount of opiates that enter Delaware through prescription pads by adding several administrative barriers such as a physical exam upon refill as well as a seven day cap on initial prescription without a well-documented rationale as to why more was prescribed.

While nationwide the epidemic continues, Delaware has taken serious steps to confront the problem. The question remains whether with a difficult fiscal year expected in 2017 funding will become available for greater treatment options on either the Federal or State level.

Telemedicine
House Bill 69 placed Delaware among the frontrunners in telemedicine in the nation. It was an expansive bill, covering many professions regulated by the Division of Professional Regulation (DPR). Various Delaware boards have been promulgating and publishing companion regulations over the last year. However, those regulations may not stand. Teladoc v. Texas Medical Board is working its way through the Texas courts over what Teladoc, a prominent direct-to-consumer telemedicine, considers an overreach by the Board in its requirement of a face-to-face visit with a patient before telemedicine can be used. The undercurrent of the question is the 2015 case North Carolina Board of Dental Examiners v. Federal Trade Commission , 135 S. Ct. 1101 (2015), which has put regulatory boards nationwide on notice that it must tread a careful line between ensuring public safety and restraining trade. Delaware's many Boards have proposed several different regulatory strategies for the professions and time will tell what the final regulations will look like.

House Bill 147 – Agency Review
A 2015 Markell Administration initiative, this legislation requires all of Delaware's agencies to solicit public input and undergo a review of their regulations for possible modification or elimination. On October 20th, the Department of Health and Social Services held a hearing regarding its regulations.

Optometry Scope Update [Note: Quoted section taken from the MJ Medical Malpractice Quarterly]
"On August 3, 2016, Governor Markell signed into law amendments to Chapter 21 of Title 24 of the Delaware Code regarding the practice of optometry. To address new optometry therapies and treatments, the new laws permit Doctors of Optometry to perform certain limited, minor procedures (not surgery or laser treatments) to the eyes. Optometrists are also permitted to prescribe certain controlled substances for limited periods consistent with the new guidelines." Although the optometry regulations were substantially updated in anticipation of the legislative change, some regulatory tweaks may be expected. The MJ Medical Malpractice Quarterly also covered those changes.

Health Data: Getting a Better Picture

All Payer Claims Database (SB 238)

One of the most important aspects of Delaware's ongoing grapple with rising health care costs is how to get an accurate picture of where Delaware is currently. Perhaps the most important legislation, although not the most attention-grabbing, to pass this session for such benchmarking is Senate Bill 238, sponsored by Senator Bethany Hall-Long and Representative Melanie George Smith. It implements Delaware's All Payer Claims Database (APCD). While not the first state to introduce or pass a version of the APCD, Delaware's version takes lessons from the other 18 or so states to have done so. Most importantly, lessons from Vermont.

But first, a brief explanation of what an APCD is. An ACPD is, as the name suggests, a database of aggregated health payment information. A major hurdle to policymakers has been an inability to drill down into the cost of care. States have been unable to adequately answer fundamental questions such as: How much is spent on health care? Does the cost change for services over time? Does it change per facility? An ACPD is a government-run aggregation of that data, captured by "claims" – essentially invoices for delivered health services – which was previously held in private hands such as insurance companies.

Vermont's, APCD prompted the Supreme Court decision Gobeille v. Liberty Mutual Insurance Company, 136 S. Ct. 496 (2015). In Gobeille, the Court held that ERISA pre-empted the state law. Vermont's law mandated that ERISA plans also share their claims data with the State's APCD. Justice Kennedy hinged the 6-2 opinion on the structure of ERISA stating that "[t]he state statute imposes duties that are inconsistent with the central design of ERISA, which is to provide a single uniform national scheme for the administration of ERISA plans without interference from laws of the several States even when those laws, to a large extent, impose parallel requirements." However, Justice Kennedy also outlined the alternate path that ERISA plans could coordinate with states saying that "the Secretary of Labor, not the separate States, [ ] is authorized to decide whether to exempt plans from ERISA reporting requirements or to require ERISA plans to report data such as that sought by Vermont."

No such action by the Secretary of Labor has occurred and Delaware's law is crafted to be wary of Gobeille. Delaware's APCD, housed in the Delaware Health Information Network (DHIN), will have its foundational data supplied from three major sources: the Medicaid Program, the State Group Health Insurance Program, and qualified plans in the Delaware Health Insurance Marketplace. It also makes provisions for accepting data voluntarily supplied from other sources.

This data will underlie many decisions being made by the Delaware Center for Health Innovation, the entity driving the use of the 2013 $36 million grant Delaware received from the Center for Medicare & Medicaid Innovation under a State Innovation Models initiative.

In the care delivery transformation talks, there does remain an unresolved question of whether claims data is the best data to reflect how Delawareans currently receive their care. Claims data lags behind the real time and paints an imperfect picture of all Delawareans' health. It's never wise to let the best be the enemy of the good, but opportunities keep being missed to aggregate clinical as opposed to mere claims data through entities such as the DHIN, which would give a real time look at how healthy Delawareans are, not just the claims being submitted to those who are insured. While claims data is certainly still useful, alone this data risks beating on health care providers who have to serve the indigent by law. Such measures subsequently risk deterring from Delaware doctors and nurses who can go work anywhere from Jefferson to Johns Hopkins here in the Mid-Atlantic.

Workflow Change: Prior Authorization

Pre-Authorization (HB 381)

Nearly hand-in-hand with Senate Bill 238, House Bill 381, sponsored by Representative Paul Baumbach and Senator Margaret Rose Henry, looks not at the back end claims data, but to the front end. A pre-authorization is a requirement by a carrier or health insurance plan that states clinicians need to submit a treatment plan, service request, or other notification to the insurer for evaluation of appropriateness of the plan, or to ensure the service is "medically necessary" before treatment is rendered. Its purpose is to limit unnecessary care. It is also an area that, if properly tracked, can strongly indicate where some of the most expensive care is being used. This bill directs this data into the DHIN at six-month intervals, which can better track what procedures, treatments, and pharmaceuticals are being requested for care

Unlike SB 238, HB 381 is not just a data gathering bill. It creates stricter timelines for getting a response to a properly-submitted pre-authorization; incentivizes the use of electronic pre-authorization by setting even shorter timelines for electronic submissions; calls for publication of pre-authorization requirements; curbs the use of retrospective denials; and creates objective criteria for the length of time a pre-authorization is valid. However, the data that is collected and will begin to be produced in June of 2017 will certainly draw the eye of policymakers as they continue to look for ways to streamline health delivery for Delawareans and bring down costs.

Behavioral & Mental Health: Rolling Back Limits on New Facilities Down the Road?

States across the country are suffering from a lack of behavioral and mental health services. Delaware is no exception. Significantly, we see signs that regulatory hurdles to new mental health facilities may be lowered. The latest in a parade of reports on the crisis comes from , Senators Hall-Long and President Pro Tem Senator Blevins who co-chaired the Behavioral and Mental Health Task Force last session. After months of work, the Task Force produced both a report and a package of bills:

1. Behavioral and Mental Health Commission (SB 245)
   Senate Bill 245 sponsored by Senator Hall-Long extends the work of the Task Force into a Commission. It also creates a Peer Review Subcommittee which reviews incident reports and treatment records, fulfilling the settlement agreement between Delaware and the Department of Justice regarding operations of the Delaware Psychiatric Center.

Additional measures codified the Suicide Prevention Coalition (SB 281) and provided for Post-Partum Education (SB 197). Additional legislation was contemplated that would have created stricter rules for connecting patients to mental health resources, but these bills were redirected as the Task Force learned of the shortcomings in the mental health services available to Delawareans. Look for efforts through telemedicine, network adequacy, and recruitment to patch gaps and stretch the limits of the mental and behavioral health care network.

Note that the state also recently issued a new RFP to support adoption and expansion of behavioral health electronic medical records.

2. Swan song for Health Resources Board? Sun Behavioral (SB 226)
   This legislation, also sponsored by Senator Hall-Long, removed the Sun Behavorial 90-bed psychiatric hospital from the requirements of additional Health Resources Board review. This bill is not without precedent. A bill from the previous session also allowed a project to sidestep the Health Resources Board. The question that arises from these bills is whether or not the Health Resources Board, which is due for Sunset Review next year, is a system losing favor.

Lastly, although not an official Task Force Bill, so not included in the list, is Senate Bill 251 sponsored by retiring Senator Karen Peterson. This bill revisits Delaware's mandatory child abuse reporting laws and seeks to allow adults who were abused as children to enter mental health care without triggering the reporting statute. While the bill came out of committee in the Senate, it did not come to the floor for a vote. Delaware has some of the most far-reaching mandatory reporting laws in the nation and a balance with patient care has proved challenging. It is unclear if the bill will be revisited in the 149th General Assembly due to law enforcement opposition, but those who provide counseling services at Delaware's colleges and universities and other mental health professionals should watch for any new requirements.

Marijuana: No Laws Over the Line

Over this election cycle, legalization of marijuana has played a role in several campaigns on both sides of the aisle. Republican Gubernatorial candidate Colin Bonini and Democratic Lieutenant Governor candidate Brad Eaby both have pushed for legalization. In the legislature, Sen. Margaret Rose Henry has called for legalization and has said she has plan to introduce a legalization for adults bill in 2017.

In the meantime, the legislature continues with incremental change in this area. In the medical marijuana arena, new Compassion Centers in Kent and Sussex are planned. Physicians remain wary of prescribing and legislators hesitate to fully embrace marijuana as a legitimate drug. The legislature passed two more bills regarding who can use medical marijuana.

The first, Senate Bill 181 sponsored by Senator Lopez, Speaker Schwartzkopf, and Representative Ramone, is an extension of "Rylie's Law" that passed in 2015. Rylie's law added access to cannabidiol oils for children with epilepsy. Senate Bill 181 allows parents onto school grounds to administer the oils. Interesting to note, school personnel such as nurses are exempt from administering the oils, which highlights tension among clinicians as to the actual efficacy of medical marijuana. And, as always, the ever-looming federal designation of marijuana as a Schedule I drug with "no currently accepted medical use" continues: a position affirmed as recently as August 11th when the Drug Enforcement Administration again refused requests to remove or down-schedule marijuana.

The second bill is House Bill 400, sponsored by Representative Paul Baumbach as well as Representative Ramone, Senator Henry, and Senator Lopez. It extends access to medical marijuana to those with a terminal illness and minors who suffer pain, anxiety, or depression related to a terminal illness.

Overall, anyone in the medical marijuana market in Delaware, including those using, prescribing, growing, leasing warehouse space, etc., continue to walk a fine line legally in Delaware, and steps over it under federal law. Not a problem Delaware can solve unilaterally.

Noteworthy Nationally: Department of Justice Intervenes in Insurance Mergers

Over the summer the US Department of Justice sued to stop the Anthem's proposed acquisition of Cigna, valued at $54 billion, and Aetna's proposed acquisition of Humana, valued at $37 billion. Underpinned in part by a significant American Medical Association study that refuted the claim that mergers lowered prices and increased access, the DOJ raised concerns in their contemporaneous press release that the mergers "would harm seniors, working families and individuals, employers and doctors and other healthcare providers by limiting price competition, reducing benefits, decreasing incentives to provide innovative wellness programs and lowering the quality of care."

Attorney General Matt Denn along with eleven other states has joined the suit. Locally, however, there is an interesting question regarding the Delaware insurance market. While Highmark remains the dominant player in Delaware, Aetna does retain a market presence. While many variable preclude judging accurately how the acquisition would affect Delaware, were the acquisition to move forward it could mean a stronger market competition for Highmark.

State Employees: Innovative Care Ahead?

The State Employee Benefits Committee (SEBC) has issued an August Request for Proposals for the state employees' Group Health Insurance Plan (GHIP) third party administrator. With approximately 20-25% of Delaware's insured lives falling into this plan, the decisions on how health care will be delivered to this group will be a major market driver. In the past, the contract has been awarded with strong consideration towards the bidder's experience and bottom-line cost. In this iteration, there is an eye towards seeking a bidder who will bring technology tools to leverage existing resources and integrate them into forward-thinking health policies that could result in a healthier workforce, bending the cost curve, and not simply re-allocating costs and kicking the can down the road.

Morris James Healthcare Industry Team News

Morris James is now the only Delaware law firm with two partners, Kimberly Hoffman and Bruce Tigani, recognized as a Delaware Top Lawyer in Health Care by Delaware Today magazine. Click here for the full story. Team member Jim Gallagher will become a firm partner on January 1, 2017.

Adam Geber Joins Morris James LLP

Adam C. Gerber is now a member of the firm's Tax, Estates and Business Practice, and the Healthcare Industry Team. His practice focuses primarily on estate planning and administration, elder law, and business matters. Adam has practiced law since 2005 in the areas of estate planning, real estate, and civil litigation including trust and estate litigation. He began his career as a Judicial Law Clerk to the Honorable William L. Witham, Jr., the Honorable James T. Vaughn, Jr. and the Honorable Robert B. Young in the Superior Court, Kent County, Delaware.

Contributors and Healthcare Industry Team Members

A. Kimberly Hoffman, Partner
Chair of Morris James Healthcare Team
khoffman@morrisjames.com
Phone: 302.888.5209
Click for Biography

Bruce W. Tigani, Partner
Morris James Healthcare Team
btigani@morrisjames.com
Phone: 302.888.6962
Click for Biography

James J. Gallagher, II, Attorney
Morris James Healthcare Team
btigani@morrisjames.com
Phone: 302.888.6962
Click for Biography

Andrew B. Wilson, Attorney
Healthcare Team Member
awilson@morrisjames.com
Phone: 302.888.6878
Click for Biography

Joshua H. Meyeroff, Attorney
Healthcare Team Member
jmeyeroff@morrisjames.com
Phone: 302.888.6901
Click for Biography