# Health Law Developments

*The Newsletter of the Health Law Section*
*State Bar of Georgia*
*Summer 2022*

## Inside This Issue



## From the Chair

Dear Health Law Sections Members:

WE DID IT! After over two years of COVID-19-imposed virtual meetings, the Health Law Section held a successful in-person Lunch and Learn – *Telehealth in Georgia: Yesterday, Today and Tomorrow*. Thank you to Wade Miller and Alston & Bird for hosting; to our distinguished panel, including Vimy Devassy, Brian Dowd, Lindsey Lonergan, and Sean Sullivan, for sharing their knowledge; and to all of you for sticking with us as we navigated the pandemic.

COVID-19 has not kept us from continuing to support the state's health law students. In April, we awarded three *Alan Rumph Memorial Fellowships* to Georgia law students accepting unpaid summer internships in health law positions with public interest organizations, government agencies, or nonprofits. This year's recipients are:

- **Rebecca Sohnlein**, Georgia State University College of Law – Internship with the Georgia Department of Community Health

- **Robert Crommelin**, Emory University School of Law – Internship with the Georgia Department of Behavioral Health and Developmental Disabilities, Office of Legal Services

- **Katie Wooten**, University of Georgia School of Law – Internship with the Health Law Partnership (HeLP)

Thank you to Aaron Danzig for working with the universities and leading us through the application and award process.

As usual, this edition of the newsletter is packed with timely articles authored by your health law colleagues. I am grateful for the leadership of Dawn Benson, Beth Stephens and Scott Grubman for keeping us on task and putting together this publication. It is this type of initiative that garnered the Health Law Section the *2022 Award of Achievement* from the State Bar of Georgia. Congratulations to the Executive Committee and especially to Rebecca Merrill, our Past-Chair, for this honor.

We have more great educational and networking programs coming up for the second half of the year, including the in-person Advanced Health Law Seminar and Annual Section Meeting to be held this Fall. The Section's Mentorship Program is also working on getting back up and running after a brief hiatus. Be on the lookout for information on these and other programs in near future.

One way you can make sure that you stay up to date on all the Section activities is by joining our LinkedIn page at: https://www.linkedin.com/groups/12211847/. If you are interested in becoming more involved in the Section, please email me at kconley@gha.org.

Warm regards,

Keri F. Conley, Chair, Health Law Section

# Will Tennessee's Criminalization of Nursing Mistakes Quash Quality Improvement Through Peer Review In Georgia?

**By Laura E. Little**

On March 25, 2022, a Tennessee nurse was convicted of criminally negligent homicide and impaired adult abuse for mistakenly administering the wrong medication to a hospital inpatient. When the nurse went to retrieve the medication from a locked, computerized medication cabinet, she removed and administered a paralytic instead of the prescribed sedative—resulting in the death of the patient. Immediately following the nurse's conviction, the American Nurses Association (ANA) and Tennessee Nurses Association (TNA) issued a joint statement, decrying the verdict.[1] They noted the "harmful ramification of criminalizing the honest reporting of mistakes", particularly for peer review and quality improvement processes going forward.[2]

Nurses nationwide have expressed concern that Tennessee's decision to criminally prosecute the nurse for a practice mistake, rather than civilly for professional malpractice, could be repeated elsewhere. Such fears are driving some nurses to quit. Others who remain in the profession have expressed reluctance to self-disclose errors or cooperate in future peer review and quality improvement processes for fear of building a case for their own prosecution. But, should nurses in Georgia have such fears?

With the Vaught Case[3] ("Vaught") in mind, this article reviews Georgia's current Peer Review Statutes[4] and the degree of protection they afford nurses. While nurses are protected equally to physicians and other healthcare professionals in Georgia, the limited scope of Georgia's Peer Review Statutes could prove inadequate in the wake of Vaught. Vaught is not binding precedent in Georgia, yet, the fear it instills in providers could nonetheless disrupt the efficacy of Georgia's Peer Review Statutes in promoting the honest self-reporting critical to peer review and quality improvement processes. As discussed below, the carefully circumscribed limits in GA's Peer Review Statutes, after Vaught, may be inadequate to promote the candor required to discover, rectify, and cure practice mistakes and systemic errors. Beyond quality, Vaught could also negatively impact nursing and patient care in other ways.

**Summary of Tennessee Case:**

In Vaught, the nurse was working her second consecutive day shift over a holiday when the incident spurring her prosecution occurred.[5] The nurse was tasked as an "Help All Nurse" to the hospital's two neuro units, with a newly-hired nurse shadowing.[6] Mid-shift, one of the nurse's assigned patients, being treated for a brain injury, was prescribed a sedative for a PET Scan to be completed before discharge.[7] When the nurse went to retrieve the drug from a locked computerized medication cabinet, she obtained and administered a paralytic instead of the prescribed sedative, resulting in the death of the patient.[8]

After the patient coded, the nurse verbally reported her error to colleagues.[9] Months later, the nurse agreed to an interview with the Tennessee Bureau of Investigation ("TBI"). After being Mirandized and electing to talk without legal counsel present, the nurse recounted to TBI investigators the series of events leading to the patient's death.[10] The nurse stated that when she went to retrieve the medication, she couldn't locate the prescribed drug under the patient's profile in the medication cabinet, so she verified the prescription and overrode the cabinet's system to pull the drug she thought was prescribed.[11] The report details various other factual admissions by the nurse, which were admitted into evidence at trial through the nurse's interview. Collectively, the facts were held to rise to criminally negligent homicide and impaired adult abuse.

It is unclear from publicly available documents what peer review processes occurred and if, or how, any peer review materials or findings were used in the

criminal case. Such materials may not have been necessary to prosecute, given the other evidence available from the nurse's admissions.

**Peer Review Privileges Generally:**

Peer review protections vary dramatically across states[12], but uniformly exist to promote continual improvement in the quality of care delivered to patients. The clinical peer review process is a longstanding tradition in medicine.[13] It's designed to permit providers to scrutinize and provide retrospective feedback regarding clinical care in a confidential setting so that they can openly discuss, identify, and avoid repeating practice mistakes.[14] Besides promoting clinical learning, such processes are critical to finding and rectifying systemic errors.[15]

Georgia courts have long recognized that peer review proceedings and medical review proceedings cannot function effectively without openness and candor among providers and that such would not exist without confidentiality.[16] Yet, Georgia, like other states, has grappled with the need to balance two competing public interests in crafting peer review privileges: (i) the need to guarantee a sphere of confidentiality around peer review processes (to enable honest self-investigation and growth by providers without fear of legal consequence) with (ii) the need to admit certain evidence into trial (to guarantee due process rights).[17] Such balancing has resulted in a necessarily limited peer review privilege in Georgia.

**Peer Review Protections in Georgia:**

Georgia's Peer Review Statutes[18] apply equally to nurses, physicians and other healthcare professionals[19]; yet, the protections they extend are qualified in scope in key ways to promote the above-noted balance. First, Georgia's Peer Review Protections[20] are restricted to ***civil actions***. Georgia's statutes do not extend similar confidentiality protections to protect peer review[20] or medical review committee[21] information from discovery or admission into ***criminal actions***, like Vaught.[22] Further, the statutes don't protect documents or evidence that are ***originally sourced*** (sourced from outside the peer review process) from discovery and admission into evidence at any trial (civil or criminal) just because they were presented to a Review Organization or Medical Review Committee.

Briefly, Georgia's Peer Review Protections may be summarized as follows:[23]

- First, Georgia's Peer Review Statutes require the proceedings and records of a Review Organization or Medical Review Committee to be held in confidence by the Review Organization or Medical Review Committee and bar their discovery or introduction into evidence in civil actions.[24] Yet, the statutes don't extend similar discovery and evidentiary protections to peer review materials in criminal actions. (Statutes are silent regarding criminal actions.)

- Second, Georgia's Peer Review Statutes bar anyone who participated in a Review Organization's or Medical Review Committee's meetings from testifying in any civil action regarding its activities or conclusions. Specifically, O.C.G.A. §31-7-133(a) provides, in relevant part: "*no person who was in attendance at a meeting of such organization shall be permitted or required to testify in any such civil action as to any evidence or other matters produced or presented during the proceedings or activities of such organization or as to any findings, recommendations, evaluations, opinions, or other actions of such organization or any members thereof.*" O.C.G.A. §31-7-143 provides similarly for Medical Review Committee meetings. The statutes absolutely bar such testimony in civil actions. Yet, they are silent regarding criminal actions, suggesting those testifying in peer review meetings may also testify in criminal actions regarding such matters.

- Third, Georgia's Peer Review Statutes expressly allow documents and testimony that were originally sourced to be admitted into civil "actions, irrespective of their use or reference in peer review proceedings. Specifically, the statutes provide that any information, documents, or records from Review Organization or Medical Review Committee proceedings that are otherwise available from an original source are not immune from discovery or admission in a civil action merely because they were presented during those proceedings.[25]

When viewed collectively, Georgia's Peer Review Statutes extend no confidentiality or evidentiary protections to Peer Review Materials in *criminal actions*. Thus, any items/information disclosed by a healthcare provider, including a nurse, in a peer review proceeding could be discoverable and admissible in a criminal action instituted against the provider.

Before Vaught, limiting Georgia's Peer Review Protections to civil actions had minimal negative consequence for peer review processes and resulting quality improvement efforts. Although Georgia's Peer Review Statutes extended no protections to peer review materials in criminal actions, a provider's criminal prosecution for a practice mistake was a statistical improbability. The law, therefore, minimally deterred nurses from participating in peer review. After Vaught, however, criminal prosecution has become a credible reality. After Vaught, the gap in protections for criminal actions could feasibly deter Georgia's nurses and other providers from fully and effectively participating in peer review proceedings for fear that anything they disclosed could underlie their or their colleagues' future prosecution. Facing such penalties, nurses are less likely to volunteer or "remember" incriminating details in peer review proceedings that are critical to practice improvement.

The Vaught case—in trying a nurse criminally for what was previously, unquestionably a malpractice tort—crossed a line. It violated the balance carefully crafted between the two competing objectives of Georgia's Peer Review Protections—promoting quality improvement and ensuring due process for victims of medical error—and in the process likely quashed it. Although Vaught has no precedential value in Georgia, it, nonetheless, may carry impact. Before Vaught, nurses risked disciplinary action by candidly disclosing their clinical care activities in peer review. Nurses could credibly weigh such (relatively minor) penalties against the gains in clinical quality and patient safety likely to result from peer review and decide their participation in peer review was worthwhile. After Vaught, with criminal prosecution for mistakes a possibility, candid participation in peer review may simply be too risky for nurses and other providers. The fear Vaught instills in Georgia's nurses could halt the honest self-reporting critical to peer review and quality improvement initiatives going forward. If so, quality will suffer.

**Laura Little** is a Shareholder in Polsinelli, P.C.'s Healthcare Practice and practices out of the Atlanta office. Her practice focuses on helping providers across the healthcare spectrum navigate the ever-changing regulatory healthcare landscape, including matters of operational compliance, reimbursement, and contracting. Laura regularly counsels physicians, hospitals/health systems, ambulatory surgery centers, and other providers across the healthcare continuum in a variety of regulatory and transactional matters, including buying/selling physician practices, hospital transactions, provider contracting (employment, services, call coverage agreements, etc.), professional and facility licensure matters, Medicare/Medicaid compliance, and telehealth. Laura received her J.D. and M.B.A. from the University of Georgia and is a Phi Beta Kappa graduate of the University of North Carolina at Chapel Hill.

## Endnotes

1. *See* "Statement in Response to the Conviction of Nurse RaDonda Vaught", Tennessee Nurses Assoc. and American Nurses Assoc. (March 25, 2022) *available at* https://www.nursingworld.org/news/news-releases/2022-news-releases/statement-in-response-to-the-conviction-of-nurse-radonda-vaught/.
2. Id; *See also* Robyn Begley, "Statement in Response to the Conviction of Nurse RaDonda Vaught", American Hospital Association (March 28, 2022) ("The verdict in this tragic case will have a chilling effect on theulture of safety in health care. . . . They discourage health caregivers from coming forward with their mistakes, . . . ") available at https://www.aha.org/public-comments/2022-03-29-aonl-statement-response-conviction-nurse-radonda-vaught#:~:text=They%20discourage%20health%20caregivers%20from,for%20patients%20during%20the%20pandemic.
3. State of Tennessee vs. Radonda L. Vaught, Criminal Ct. for Davidson County, Division IV, Case No. 2019-A-76.
4. *See* O.C.G.A. §31-7-1130 et seq. (for peer review groups) and O.C.G.A. §31-7-140 et seq. (for medical review committees) (collectively, hereinafter, the "Peer Review Statutes").
5. *See* TN Bureau of Investigation, Investigative Report for Case # NA-16A-000156 (Report Date: March 19, 2019) available at https://ewscripps.brightspotcdn.com/3d/46/feb995d34e9782f9ae33e37391c0/0716-001.pdf.
6. *Id*.
7. *Id*.
8. *Id*.
9. *Id*.
10. *Id*.
11. *Id*.
12. *See* Lindor, Campbell, Reddy and Hyde, *State Variability in Peer Review Protections Heightens Liability Risks*, Mayo

Clin Proc Inn Qual Out (April 2021) available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8105528/pdf/main.pdf. (noting the "widespread variability in state-based peer review protections").

13. *Id*.
14. *Id*.
15. *Id*.
16. *See* Ga. Law of Torts Preparation for Trial 24:11 (2nd ed.) *citing* Eubanks v. Ferrier, 245 Ga. 763, 765, 267 S.E.2d. 230 (1980). ("[p]eer and medical review proceedings cannot function effectively without openness and candor, and the information therein is privileged to ensure that the required candor is maintained.").
17. *See* Ga. Law of Torts – Trial Preparation and Practice § 24:11 ("The peer review and medical review statutes seek to strike a balance between the competing interests of promoting candor within review proceedings and allowing medical malpractice plaintiffs open access to evidence.")
18. *See* O.C.G.A. §31-7-1130 et seq. (for peer review groups) and O.C.G.A. §31-7-140 et seq. (for medical review committees) (collectively, hereinafter, the "Peer Review Statutes").
19. *See* O.C.G.A. §31-7-131(2) (defining "professional health care provider" for purposes of peer review protections as individuals licensed to practice in the health care field in Georgia, including but not limited to physicians, dentists, podiatrists, chiropractors, optometrists, psychologists, pharmacists, registered nurses or practical nurses, physical therapists, occupational therapists, hospital/health care facility administrators and others.)
20. References to "Georgia's Peer Review Protections" include the protections provided under O.C.G.A. §31-7-130 et seq. (for Review Organizations) and O.C.G.A. §31-7-140 et seq. (for Medical Review Committees).
21. Georgia statutes refer to peer review committees as "Review Organizations"; O.C.G.A. §31-7-131(3) (defines a "Review Organization" to include, in relevant part: "any panel, committee, or organization: (A) Which: (i) is primarily composed of professional health care providers; . . .and (B) which engages in or utilizes peer reviews and gathers and reviews information relating to the care and treatment of patients for the purposes of: (i) Evaluating and improving the quality and efficiency of health care rendered; (ii) Reducing morbidity or mortality; . . .(vi) Performing any of the functions or activities described in O.C.G.A. 31-7-15.").
22. O.C.G.A. §31-7-140 (defines a "medical review committee" to mean "a committee of a state or local professional society or of a medical staff or a licensed hospital, nursing home, medical foundation, or peer review committee, provided the medical staff operates pursuant to written bylaws that have been approved by the governing board of the hospital or nursing home, which committee is formed to evaluate and improve the quality of health care rendered by providers of health service or to determine that health services rendered were professionally indicated or were performed in compliance with the applicable standard of care or that the cost of health care rendered was considered reasonable by the providers of professional health services in the area.")
23. While O.C.G.A. 31-7-132(a) provides "No professional health care provider . . . shall be held, by reason of the performance of peer review activities, to have violated any criminal law or to be civilly liable under any law, unless he was motivated by malice toward the person affected by such activity", the protection from criminal liability applies only to crimes arising from the participation in the peer review activities, not from actions occurring outside of peer review that may be investigated in peer review.
24. Georgia's statutes impose similar qualified protections for Medical Review Committee proceedings as those for Review Organizations. Specifically:
    First, Georgia's statutes provide that "*the proceedings and records of medical review committees shall not be subject to discovery or introduction into evidence in any civil action against a provider of professional services arising out of the matters which are the subject of evaluation and review by such committee*." O.C.G.A. §31-7-143. As with Review Organization statutes, this protection is expressly limited to civil actions and further limited to those civil actions arising out of the subject matter of the Medical Review Committee's review. It doesn't extend the protections to other civil or criminal actions.
    Second, Georgia's statutes bar anyone who was in attendance at a Medical Review Committee meeting from testifying in any civil action arising out of the matters which are the subject of evaluation and review by the committee regarding any evidence or other matters produced or presented during such committee proceedings or any findings, recommendations, evaluations, opinions, or actions of such committee or its members. *See* O.C.G.A. §31-7-143. This statue doesn't bar Medical Review Committee attendees from testifying in criminal actions regarding items produced in the committee or the committee's findings and actions.
    Third, Georgia's statutes expressly allow documents and testimony that stand as original sources to be admitted into civil actions, and therefore imply their admissibility in criminal actions. Statutes provide: ". . . *information, documents, or records otherwise available from original sources shall not be construed as immune from discovery or use in any such civil action merely because they were presented during proceedings of such committee; nor shall any person who testifies before such committee or who is a member of such committee be prevented from testifying as to matters within his knowledge; provided that, such witness may not be questioned regarding his testimony before such committee or opinions formed by him as a result of such committee hearing*." O.C.G.A. §31-7-143.
25. O.C.G.A. §31-7-133(a) ("Except in proceedings alleging violation of this article, the proceedings and records of a review organization shall be held in confidence and shall not be subject to discovery or introduction into evidence in any civil action. . .").
26. O.C.G.A. §31-7-133(a) (. . . However, information, documents, or records otherwise available from original sources are not to be construed as immune from discovery or use in any such civil action merely because they were presented during proceedings of such organization, nor should any person who testified before such organization or who is a member of such organization be prevented from testifying as to matters within such person's knowledge; but such witness cannot be asked about such witness' testimony before such organization or about opinions formed by such witness as a result of the organization hearings. . .").

# The Department of Justice Continues Its Intense Scrutiny of the Clinical Laboratory Industry

**By Ellen H. Persons**

Although laboratory testing is essential for the proper treatment of patients, these tests are also often expensive. Where there is money, there is fraud – at least in the eyes of the Department of Justice ("DOJ"). As such, the clinical laboratory industry continues to be under increasing scrutiny by the DOJ. From genetic testing schemes to urine drug testing, and a continued focus on sales and marketing relationships in violation of the Anti-kickback Statute ("AKS") and the Eliminating Kickbacks in Recovery Act ("EKRA")[1], laboratories are getting hit from all directions. Now, with the pandemic seemingly nearing an end, COVID testing is certain to be the next to come under the DOJ's microscope.

With this ever-increasing attention, having a robust and active compliance program and obtaining timely legal advice is key to avoiding DOJ/OIG scrutiny.

**Genetic Testing Schemes**

In the past few years, genetic testing has become increasingly popular. For example, Pharmacogenetic/pharmacogenomic ("PGx") tests are used to identify genetic variations that may predispose a patient to an unusual reaction to medications. Cancer genetic screening ("CGx") tests are used to show whether a patient has a genetic predisposition to certain types of cancer. Genetic testing fraud often occurs when the Medicare program is billed for testing or screening that is not medically necessary or was not ordered by the beneficiary's doctor. These tests are often extremely expensive and, despite Medicare's limited coverage, Medicare payments for genetic tests more than doubled between 2015 and 2018 to over $1 billion in payments in 2018.[2]

In 2019, the DOJ kicked off "Operation Double Helix" – targeting telemarketing, telehealth companies, and labs engaged in fraudulent genetic testing. While much of the enforcement in the genetic testing space to date has been on the criminal side, the DOJ has also used the federal False Claims Act ("FCA") and AKS to target labs involved in fraudulent genetic testing schemes.

For example, the DOJ announced an FCA settlement on February 11, 2019, with GenomeDx Biosciences Corporation for $1.99 million to resolve allegations that the genetic testing company submitted claims for genetic tests that were not medically reasonable and necessary because the prostate cancer patients who received the tests did not have any of the specific risk factors that qualified for the testing.[3]

In October 2019, the DOJ announced another FCA settlement of $42.6 million with a genetic testing company, UTC Laboratories Inc., and three of its principals, relating to allegations that the laboratory paid kickbacks to doctors as well as marketers and also billed for medically unnecessary genetic tests.[4]

On January 6, 2021, the DOJ announced an FCA settlement of $357,584 with Exceltox, a California diagnostic laboratory, to resolve allegations that it persuaded groups of senior citizens in senior housing complexes to submit to genetic testing, despite Medicare rules requiring orders for genetic tests to come from treating physicians.[5]

Allegations in these civil case examples often closely reflect those seen in criminal enforcement cases, but usually involve less egregious conduct (or, at least, less egregious evidence). It is likely we will begin to see additional civil settlements in this space.

**Urine Drug Testing ("UDT")**

With the continued opioid epidemic, there has been an increasing focus on not only prescribing physicians, but also on laboratories conducting UDT. There are two types of UDT at issue in the cases being pursued

by the DOJ. The first is called presumptive testing, which is also referred to as qualitative, preliminary, or screening tests. Presumptive tests are used to determine the presence or absence of a drug in the urine. These tests are simple to perform and can be done through point of care ("POC") testing at a physician's office or at a clinical laboratory. The second type of test is called definitive testing, which is also referred to as quantitative or confirmatory testing. These tests can only be performed in a clinical laboratory and identify a broader list of specific drugs as well as the presence of metabolites, indicating whether the drug has been ingested.

The DOJ has focused its efforts on prosecuting laboratories that are running both presumptive and definitive testing on the same day and reporting the results to a physician at the same time. The DOJ's position is that, by reporting both results at the same time, a physician has no opportunity to review the presumptive test results to determine whether it is medically necessary to run the more expensive and detailed definitive test.

On April 15, 2020, the DOJ settled an FCA case with a Florida-based clinical laboratory, Logan Laboratories, Inc., and two former executives for $41 million.[6] The settlement resolved allegations by the DOJ that the defendants had developed and implemented a policy and practice of automatically ordering both presumptive and definitive UDT for all patients at every visit, without ever having a physician make an individualized determination on the medical necessity of the testing for each patient.[7]

On October 20, 2021, the DOJ settled another FCA case with a Nevada-based clinical laboratory, MD Spine Solutions LLC, d/b/a MD Labs Inc., and two of its owners and co-founders for $16 million.[8] In that settlement, MD Labs and its owners and co-founders admitted that they performed both presumptive and definitive tests at approximately the same time and then provided the results from both tests at the same time to health care providers, knowing the physicians would not review the presumptive results when they already had the more detailed and precise definitive results.[9] In doing so, the presumptive UDT results were frequently useless and the definitive UDT results were baseless because there was nothing to confirm.

Similarly, the DOJ recently settled an FCA case against a North Carolina-based clinical Lab, Radeas LLC for $11.6 million.[10] The settlement addresses almost identical conduct to that of MD Labs – performing both presumptive and definitive tests at approximately the same time and then simultaneously submitting the results for both tests to health care providers. The DOJ's view in these cases is that, absent any physician review of the presumptive UDT results, there is nothing to support the medical necessity of a separate definitive test.

In these cases, the DOJ often scrutinizes laboratory requisition forms provided to health care providers to determine whether the forms make clear that a physician is making an independent medical decision for each patient when ordering a specific test. The DOJ is also looking at whether laboratories maintain standing orders or custom testing profiles for physicians that are run on every patient.[11] The DOJ often reviews claims data and looks for outliers or patterns of billing to proactively bring cases on their own. The DOJ's position is that every test ordered must involve an independent medical decision for each patient individually. Laboratories have consistently argued that they are not in the position to make a medical decision about what tests to run and that physicians should be held accountable if a test ordered is not medically necessary. While the OIG seems to have agreed with laboratories on this point, issuing guidance that states: "laboratories do not and cannot treat patients or make medical necessity determinations,"[12] the DOJ maintains, and courts have agreed, that "[l]aboratories have a legal duty to ensure that they do not submit claims for medically unnecessary tests."[13]

**COVID Testing**

Like the genetic testing schemes, much of the enforcement involving COVID-19 fraud has been on the criminal side to date.

On April 20, 2022, the DOJ announced criminal charges against 21 defendants in nine federal districts across the United States for alleged participation in various COVID-19 fraud schemes.[14] One such scheme involved two owners of a clinical laboratory in California, Matias Clinical Laboratory, Inc., d/b/a Health Care Providers Laboratory, Inc. charged with

healthcare fraud, kickbacks, and money laundering for over $214 million in fraudulent billing for laboratory tests.[15] More than $125 million of those billings involved claims for COVID-19 and respiratory pathogen tests that were "submitted without regard to medical necessity."[16]

On January 13, 2022, the owner of Boca Toxicology LLC, d/b/a Lab Dynamics pleaded guilty to bribing patient brokers who referred Medicare beneficiaries and doctors' orders authorizing medically unnecessary genetic testing to the lab.[17] Once the COVID-19 pandemic began, the lab owner began bundling COVID-19 tests with more expensive, medically unnecessary testing, including respiratory pathogen panel testing, genetic testing for heart disease, cancer, diabetes, obesity, Parkinson's, Alzheimer's and dementia, resulting in a total of $6.9 million in false and fraudulent claims to Medicare for medically unnecessary tests.[18]

As we move further away from the height of the pandemic, we will likely see an increase in civil investigations and settlements under the FCA for less egregious conduct and more complex schemes. Included in that will certainly be a focus on the misuse of CARES Act funds, including Provider Relief Funds and Paycheck Protection Program Money by laboratories and other eligible health care entities and individuals. However, we may also begin to see civil FCA COVID-19 cases based on false billings through the ordering of medically unnecessary tests and the use of kickback schemes.

**Kickback Schemes**

In addition to cases involving medical necessity, the DOJ continues to scrutinize referral schemes for testing conducted by laboratories and on laboratories paying commissions to independent sales and/or marketing contractors.

In *United States v. Mallory*, the Fourth Circuit further solidified the DOJ and OIG's position that paying a 1099 marketing or sales organization or person a percentage-based commission constitutes remuneration intended to induce sales reps to sell as many tests as possible, in violation of the AKS.[19] In *Mallory*, despite Defendants' argument that commissions to salespeople can never constitute a kickback because the sales reps do not directly refer patients to the lab, the Fourth Circuit rejected this argument, holding that the AKS expressly prohibits individuals from receiving remuneration in exchange for "arranging for or recommending purchasing" health care services (i.e. lab tests) to physicians.[20]

On January 11, 2021, DOJ entered a settlement with AutoGenomics, a California company operating a laboratory doing business as PersonalizeDx Labs for $2.5 million.[21] The settlement resolved allegations that AutoGenomics entered into agreements with a health care marketing company whereby AutoGenomics would pay a specific amount of money to the marketing company for each genetic test they referred and for which AutoGenomics was reimbursed by Medicare in violation of the AKS.

In March 2021, the owner of a urine drug testing laboratory in North Carolina, Physicians Choice Laboratory Services, LLC, paid $2 million to resolve FCA and AKS allegations that he participated in a scheme that provided urine drug testing equipment, volume-based commissions to 1099 sales reps in exchange for influence over physician practices, and loans to induce referrals for definitive UDTs.[22]

In the District of New Jersey, several individuals who owned Metpath, a clinical laboratory that billed Medicare for COVID-19 testing, were recently charged with criminal violations of the AKS for paying kickbacks to marketers who supplied thousands of COVID-19 tests to Metpath.[23]

**Conclusion**

All of these cases demonstrate the continued focus of the DOJ on clinical laboratories. To avoid scrutiny from the DOJ, laboratories should pay close attention to how tests are run and billed, ensuring there is support for medical necessity. Laboratories should also review the compensation structure of their sales reps arrangements to ensure compliance with the AKS and EKRA. Having a robust and active compliance program and seeking legal advice where appropriate is key to avoid coming under the DOJ's microscope.

**Ellen H. Persons** is a shareholder in the Government Investigations group at Polsinelli. Her practice focuses on representation of corporate and individual clients in civil and criminal investigations by the Department of Justice (including several involving laboratory testing), regulatory investigations, as well as conducting internal investigations.

## Endnotes

1. EKRA, 18 U.S.C. § 220, is a relatively new law, enacted in 2018 as part of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (the "SUPPORT Act"). EKRA targets patient brokers who improperly profit illegal patient referrals by prohibiting laboratories, clinics, recovery centers, and other clinical treatment facilities from accepting or paying kickbacks for such referrals. Because there have been very few prosecutions under EKRA, this article focuses mainly on the AKS. However, providers should be aware that conduct that violates the AKS may also be violative of EKRA.
2. Sarah N. Lynch, *Special Report: New Frontier in Health Fraud - Genetic Tests of the Elderly*, REUTERS (Sept. 25, 2019), https://www.reuters.com/article/us-usa-fraud-genetics-specialreport/special-report-new-frontier-in-health-fraud-genetic-tests-of-the-elderly-idUSKBN1WA2H1.
3. *See* DOJ Press Release, San Diego Genetic Testing Company Agrees to Pay $1.99 Million to Resolve Allegations of False Claims to Medicare for Medically Unnecessary Tests, *available at* https://www.justice.gov/usao-sdca/pr/san-diego-genetic-testing-company-agrees-pay-199-million-resolve-allegations-false.
4. *See* DOJ Press Release, Genetic Testing Company and Three Principals Agree to Pay $42.6 Million to Resolve Kickback and Medical Necessity, *available at* https://www.justice.gov/opa/pr/genetic-testing-company-and-three-principals-agree-pay-426-million-resolve-kickback-and.
5. *See* DOJ Press Release, California Genetic Testing Lab Agrees to Pay $357,584 to Resolve False Claims Act Allegations, *available at* https://www.justice.gov/usao-nj/pr/california-genetic-testing-lab-agrees-pay-357584-resolve-false-claims-act-allegations.
6. *See* DOJ Press Release, Florida-Based Laboratory, Pain Clinic, and Two Former Executives Agree to Pay $41 Million to Resolve Allegations of Unnecessary Drug Testing, available at https://www.justice.gov/usao-edpa/pr/florida-based-laboratory-pain-clinic-and-two-former-executives-agree-pay-41-million.
7. *Id*.
8. *See* DOJ Press Release, MD Labs and its Co-Founders Agree to Pay Up to $16 Million to Resolve Allegations of Fraudulent Billing, available at https://www.justice.gov/usao-ma/pr/md-labs-and-its-co-founders-agree-pay-16-million-resolve-allegations-fraudulent-billing.
9. *Id*.
10. *See* DOJ Press Release, Radeas LLC Agrees to Pay $11.6 Million to Resolve Allegations of Fraudulent Billing, *available at* https://www.justice.gov/usao-ma/pr/radeas-llc-agrees-pay-116-million-resolve-allegations-fraudulent-billing.
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12. OIG Compliance Program Guidance for Clinical Laboratories, 63 Fed. Reg. 45,079 (Aug. 24, 1998); *see also* 42 C.F.R. 410.32, providing that the physician treating a beneficiary has the responsibility for providing medical necessity for laboratory diagnostic tests.
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# Risk Management Considerations for Physician Practices When Responding to a Medical Device Recall Notice

**by Raj Shah and Hayley Tate**

The Food and Drug Administration (FDA) is the federal regulatory agency authorized to approve medical devices. All medical devices carry some risks, and sometimes either the FDA or the device manufacturer determines that the risks outweigh the benefits and issues a medical device recall notice. According to the FDA, over 10 million medical devices were recalled in 2020.[1]

A medical device recall is a method of removing or correcting medical devices that violate FDA laws.[2] A recall is initiated when the manufacturer either makes a correction or removes the device from where it is used or sold.[3] The Safe Medical Devices Act (SMDA) requires manufacturers to report device-related deaths, serious injuries, and malfunctions to the FDA.[4] Before issuing a possible recall to patients, physicians, or the public, manufacturers will often weigh: (1) the possibility of mitigating the problem with an intervention, (2) probability of device failure, and (3) likelihood of harm. Most often, manufacturers will perform voluntary recalls, although the FDA has the authority to mandate a recall.[5]

When a manufacturer decides to initiate a recall or a potential recall, the manufacturer will notify the FDA. The FDA then conducts a health hazard evaluation and classifies the medical device as either a Class I, Class II, or Class III recall, based on the risk the medical device poses to patient safety:[6]

- Class I – most serious, occurs when a reasonable chance exists that the product will cause serious health problems or death.[7]
- Class II – occurs when either (1) a possibility exists that the product will cause temporary or reversible health problems, or (2) a remote chance exists that the product will cause serious health problems.[8]
- Class III – occurs when little chance exists that the product will cause health problems.[9]

The recalling manufacturer is responsible for notifying each of its affected suppliers, which is generally the physician or hospital. Unless it is a direct-to-consumer product, a manufacturer will not directly notify patients.[10]

The FDA does not provide guidance on how physicians should respond to a recall notice, and there is no requirement that physicians notify their patients about the recall. Accordingly, the majority of times a manufacturer will just notify the physician (and not the patient). This creates significant concern for the physician as to whether and how they should appropriately notify and treat their patients affected by a recall in the absence of any mandated guidance from the FDA.

Upon receiving a recall notice, the physician should immediately carry out the recalling manufacturers' recommendations.

Likewise, it is important that physicians implement procedures upon notice of a recall. Establishing an appropriate response is critical for a physician to avoid any potential liability and maintain good relationships with their patients. Most facilities such as hospitals and ambulatory surgery centers have formal policies and procedures for handling recalls – physicians should follow those. The following are risk management steps that outpatient or private practice physicians should utilize upon receiving a recall notice from a manufacturer.

**Steps for Effectively Responding to a Manufacturer Recall Notice**

1. **Physicians should have a system in place before receiving a recall letter.**

Physicians should implement their own system to handle medical device recalls. Have an easily accessible tracking system to identify patients who use a particular medical device. In the event of a recall, it will enable a more efficient process in notifying patients who may be affected.

Physicians should be prepared for a high volume of patients calling to obtain further information and schedule follow-ups. Also, have a script available for answering these affected patients' calls.

**2. Physicians should schedule a meeting with the manufacturer.**

Physicians need to make sure they have all the accurate information needed from the manufacturer to effectively treat their patients and to be prepared to answer patients' questions. The manufacturer should reach out to physicians about the recall and provide them with most of this information; however, in case they do not (or if the information they provide is not to the physicians' satisfaction), consider asking the manufacturer to clearly identify:

- The product, size, lot number(s), serial number(s), and any other pertinent descriptive information to ensure quick and accurate identification of the product;
- The reason for the recall;
- Possible hazards or implications involved;
- The date range for when the product was manufactured and distributed;
- Whether there is a replacement product available;
- The manufacturer's recommendation(s); and/or
- A ready means for collection of the medical device.[11]

If physicians are not receiving the information they need from the manufacturer to their satisfaction, they should reach out to the FDA and other physicians within their specialty who are likely to have also been affected by this recall.

**3. Physicians should follow the manufacturer's recommended action steps.**

In the recall letter, the manufacturer will describe actions for safe handling of the recalled product (for example: discontinue use, discard, correct the product, or return the product). It will also state whether these actions are temporary or long-term. The following should also be included in the recall letter:

- Recommended treatment or action for users to minimize risks or impacts of the affected product;
- Actions to be taken pending correction or removal of the device;
- Alternative products that can be used.[12]

**4. Physicians should timely reach out to patients to provide follow-up care.**

Physicians have an ethical obligation to notify their patients if they believe a medical device could put their patients at risk.[13] If physicians are unable to reach a patient, they should document that they tried to reach the patient via phone or email, at least twice.

By notifying and meeting with patients, physicians maintain good relationships with their patients while reducing the possibility of a lawsuit.

**5. Physicians should pursue a course of shared decision-making with the patient.**

Consider the following topics of discussion with the patient:

- The nature of the recall;
- Possible symptoms and signs;
- Compare the risks and benefits of leaving, monitoring, or removing the medical device (and any additional procedures or treatment that may be warranted, such as follow-up visits or therapy);
- Limitations on present knowledge which cannot incorporate future discoveries or fully address all possible outcomes; and
- Financial considerations.

It is important to have open and honest communication with patients. After having this initial conversation, allow the patient time to think about which course of action they want to take. Physicians should also assure the patient that they are monitoring the situation and will keep them up to date.

**6. Physicians should stay up to date with new information and findings.**

Accurate information should remain a physician's top

priority. Patients will want up-to-date information, and this will allow them to formulate the best possible treatment plans for their patients.

For subsequent follow-up visits, procedures, and therapy, the patient or their insurer will be responsible for any services performed by their physician. Patients may have to sue the manufacturer to get reimbursed for their out-of-pocket costs. Sometimes the manufacturer will cooperate with payers to reduce costs and any financial burden placed on the patient. The physician will not be liable for such costs.

Generally, when there is a recall on a medical device, the manufacturer will be sued and not the patients' physician. A physician opens themselves up to liability by:

1. Failing to obtain informed consent from the patient;
2. Negligently installing the implant or medical device;
3. Failing to take appropriate action when they received the recall notice, and when that failure resulted in injury to the patient (That is why it is important to follow the recommended steps from the manufacturer and schedule follow-up care with the patient after receiving notice of the recall.);
4. Failing to adequately maintain records, resulting in a delay in a patient receiving care (This is a reason why it is crucial to have a complete, accurate, and accessible medical records and tracking system in place.).

Since medical device recalls occur regularly, it is important that physicians implement procedures upon notice of a recall. Establishing an appropriate response is critical for a physician to avoid any potential liability and maintain good relationships with their patients. By following the recommended steps within this article, physicians will decrease exposure to potential lawsuits. Physicians should always put their patients' safety first and lean on the side of caution. Respect, education, and shared decision-making can soothe patients' concerns about a medical device recall.

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# Lunch and Learn


# Overview of the No Surprises Act for Providers

by Brittany H. Cone and Jordan Johnson

Part of the Consolidated Appropriations Act of 2021 (H.R. 133; Division BB – Private Health Insurance and Public Health Provisions), the No Surprises Act ("NSA" or "Act") was signed into law on December 27, 2021, as part of "a bipartisan, bicameral deal . . . to protect patients from surprise medical bills and promote fairness in payment disputes between insurers and providers."[1] The NSA amended Title XXVII of the Public Health Service Act to add a new "Part E," which applies to physicians, facilities, health plans, and other providers. Broadly, the NSA restricts out-of-network providers' ability to bill patients more than the patient would have paid if treated by an in-network provider. The NSA also contains several provisions regarding price transparency, continuity of care, and payment dispute resolution.[2] Physicians, health plans, facilities, and other providers were expected to come into compliance with these new requirements beginning on January 1, 2022.[3]

**Surprise Billing, Cost-Sharing, and Notice and Consent**

The NSA contains several provisions aimed at curbing surprise billing for patients.[4] Under the NSA, providers are forbidden from balance billing[5] patients for out-of-network emergency services. Instead, patient cost-sharing is limited to a maximum of the total amount that the patient would have paid if the provider had been in-network, and health plans are required to follow a specific process for determining patient cost-sharing. This amount is based on the "recognized amount," which, based on the circumstances, can be either (1) the amount specified under state law (if applicable); (2) the qualifying payment amount ("QPA"); or (3) the amount established through an all-payer model agreement. Stated differently, the QPA will generally apply unless the state has a surprise medical billing law or an all-payer rate setting model.[6]

Georgia is one of several states that has implemented a state surprise medical billing law.[7] For some claims, this will serve as the "specified state law" that will govern the healthcare provider out-of-network reimbursement. However, Georgia's law is not as comprehensive as the NSA, and for many of out-of-network services, some of the NSA's provisions (such as the independent dispute resolution process, discussed *infra*) will be used to determine provider reimbursement.

As for certain non-emergency services, the NSA forbids providers from balance billing a patient unless the provider follows certain notice and consent criteria laid out in Section 300gg-132(d) of the Act.[8] The notice and consent process requires out-of-network providers to notify a patient of their out-of-network status and to obtain the patient's written consent to receive the out-of-network services more than seventy-two hours before the service is rendered.[9] At a minimum, the notice must contain notification that the provider is out-of-network, a "good faith estimate" of the charges, a list of in-network providers at the facility, information on any prior authorization or other care management limitations, and a clear statement that consent is optional and the patient can alternatively use an in-network provider. Facilities are required to maintain these notices for seven years after the date on which the item or service was delivered. The notice and consent exception does not apply to services such as radiology, emergency medicine, anesthesiology, pathology, or other "ancillary services" where patients are generally given less of a choice in selecting their providers.

**Price Transparency/Good Faith Estimates**

The NSA also contains several provisions relating to price transparency. For example, providers are required to "make publicly available, and (if applicable) post on a public website" certain patient protection disclosures of the protections against surprise billing, including "any other applicable [s]tate law requirements" regarding the amounts a provider may charge for services.[13] In circumstances where items or services are scheduled at least three days in

advance or upon request by the patient, providers are required to share "good faith estimates" of the total expected charges for scheduled items or services (including any expected ancillary services) and the expected billing and diagnostic codes for all items and services to be provided. There has been much debate regarding the applicability of the good faith estimate requirements to specific segments of the health care industry, including Long-term Care. To date, the Department of Health and Human Services ("HHS") and Centers for Medicare and Medicaid Services have broadly interpreted the requirements to apply to the vast majority of healthcare providers. Additionally, the NSA established a Patient-Provider Dispute Resolution process in which patients can dispute bills that are "substantially in excess" of the good faith estimate.[14]

Under the NSA, health plans are also required to maintain a publicly available provider database containing the provider's contact information, specialty, relationship with the health plan, and other information. At a minimum of every ninety days, health plans are required to verify and update the directory information as needed. Thus far, health plans have passed this burden on to in-network providers by requiring them to frequently verify the requisite information or risk not being listed as an in-network provider on the health plan's provider directory/ database.

**Enforcement Authority**

In terms of enforcement authority, the NSA vests States with the main authority to ensure provider compliance with the provisions and to enforce adherence. However, absent state action against any violation, the NSA allows the Secretary of HHS to issue civil monetary penalties of up to $10,000 per violation. The HHS Secretary can waive these penalties or issue hardship exemptions in certain circumstances.

**Payment Disputes and the Independent Dispute Resolution Process**

When services are provided by out-of-network providers and the health plan either makes an initial payment or issues a notice of denial, providers can initiate a thirty-day open negotiation period. If the provider and health plan cannot reach an agreement, the provider can then initiate the IDR process within four business days of the close of the negotiation period. The parties must select a certified IDR entity within three business days of initiating IDR and offers must be submitted within ten business days of selection. The IDR entity then has thirty days to select one of the offers and "shall" consider: (1) the parties' offers; (2) the QPA; (3) the training, experience, quality, and outcomes measurements of the provider or facility; (4) the parties' market shares; (5) the acuity of the individual receiving such item or service; (6) the teaching status, case mix, and scope of services of the provider; (7) good faith efforts by the parties to enter into a network agreement; and (8) any other relevant information submitted by either party.[15]

In cases where open negotiations fail, the NSA requires the Secretary of Health and Human Services, Secretary of Labor, and Secretary of the Treasury to establish by regulation an independent dispute resolution ("IDR") process no later than December 27, 2022 (or one year after enactment of the NSA) to handle such disputes. In turn, on September 30, 2021, HHS, the Department of Labor, and the Department of the Treasury ("Departments"), along with the Office of Personnel Management, released an interim final rule ("IFR") entitled "Requirements Related to Surprise Billing; Part II" implementing, in part, these IDR provisions.

Under the IFR, IDR entities must select the proposed payment amount closest to the QPA unless certain conditions are satisfied. This "presumption" in favor of the QPA has been the topic of much legal debate, and the United States District Court for the Eastern District of Texas, Tyler Division, recently vacated portions of the rule—reasoning that the IFR conflicts with the unambiguous terms of the NSA, and the Departments improperly bypassed notice and comment in implementing the challenged portions of the rule.[16] Regarding the IFR's conflict with the NSA, the issue lies with the factors an IDR "shall" consider in determining which offer to select. The Court reasoned that the language of the NSA was unambiguous, and "[n]othing in the Act . . . instructs arbitrators to weigh any one factor or circumstance more heavily than the others."[17] Because the language of the IFR "places its thumb on the scale for the QPA" and "impos[es] a heightened burden on the remaining statutory factors

to overcome that presumption," the IFR was in conflict with the "clear statutory terms" of the NSA.[18]

There are also multiple other pending suits between providers and provider associations against the Departments, including in the Northern District of Georgia, District of Columbia, Northern District of Illinois, and Eastern District of New York. On April 22, 2022, the Departments filed a Notice of Appeal from the Final Judgment.[19] Although the Departments had initially anticipated that a final rule would be issued no later than May of 2022, they have reassessed this timeline and now anticipate that the Final Rule will be issued by early summer of 2022.

**Tips for Provider Compliance with the NSA**

Providers should consider the following best practices in complying with the NSA:

- Create an internal system or process to determine which services and patients are subject to the surprise billing provisions of the NSA.
- Refrain from billing a patient directly until a determination has been made regarding whether the NSA's billing provisions apply.
- Establish NSA-compliant policies and procedures for giving notice and obtaining consent from willing out-of-network patients and for retaining consent forms.
- Establish policies and procedures for compliance with disclosure requirements, including determining coverage status and providing good faith estimates.
- In cases of payment disputes with insurers, note the tight deadlines for providers to initiate the IDR process.

Healthcare payment regulations are amongst the most complex legal issues around, and the NSA is no different. In fact, there remain numerous practical uncertainties related to the practical application of the NSA's provisions to the various scenarios providers experience on a regular basis. Attorneys for health care providers should be intimately aware of the NSA, its implementing rules, and the ever-changing guidance to appropriately assist providers in navigating the multiple nuances and complexities.

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**Endnotes**

1. Press Release, House Ways & Means Comm., Congressional | Committee Leaders Announce Surprise Billing Agreement (Dec. 11, 2020), https://waysandmeans.house.gov/media-center/press-releases/congressional-committee-leaders-announce-surprise-billing-agreement.
2. *See generally* Centers for Medicare & Medicaid Svs., *Overview of Public Health Service (PHS) Act Provider and Facility Requirements* (last visited Apr. 25, 2022), https://www.cms.gov/files/document/high-level-overview-provider-requirements.pdf.
3. *Id*. The Department of Health and Human Services has exercised its enforcement discretion until January 1, 2023, or later on several portions of the NSA, including the Good Faith Estimate requirements for "co-providers" and "co-facilities."
4. While outside the scope of this article, the NSA extends similar surprise billing protections to patients using air ambulance services.
5. "Balance billing" occurs "when a patient's health insurance company pays an out-of-network physician or other health care provider less than the amount the physician charges for the care. Because the physician and the health plan have not agreed upon payment through a contract, the physician bills the patient for the remainder of the costs." American Medical Association Advocacy Resource Center, *Issue brief: Balance billing* (2016), file:///C:/Users/bculverhouse/Downloads/balance-billing-issue-brief-final.pdf.
6. The QPA is generally "the median of the contracted rates recognized by the plan or issuer . . . under such plans or coverage, respectively, on January 31, 2019, for the same or a similar item or service that is provided by a provider in the same or similar specialty and provided in the geographic region in which the item or service is furnished." 42 U.S.C. §§ 300gg-111(a)(3)(E)(i)(I)–(II). Stated differently, the QPA is generally the median rate the insurer would have paid for the item or service if the provider or facility had been in-network.
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8. *See generally* 42 U.S.C. § 300gg-132.
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# The Federal No Surprises Act and the Regulations Governing Out-of-Network Payment

**By Deborah J. Winegard**

**Introduction**

On December 27, 2020, the No Surprises Act (the "Act"), which had bipartisan support, was signed into law as part of the Consolidated Appropriations Act of 2021, Public Law No 116-260. Among other things, the Act prohibits surprise bills for out-of-network cost-sharing and balance billing amounts to individuals covered by group health plans and health issuers of group and individual health insurance coverage (collectively, "Plans"): (1) when patients receive emergency services, including post-stabilization services, from a non-participating provider or facility in a hospital emergency department or a free-standing emergency department (42 U.S.C. 300gg-111(a)); and (2) when patients receive non-emergency services from a non-participating provider at a participating facility. (42 U.S.C. 300gg-111(b)). The Act does not apply to non-emergency services provided at non-participating hospitals.

The regulations implementing the Act took effect January 1, 2022. At the same time, one of the most important aspects of the regulations – the standard by which payment to out-of-network providers under the Act should be determined – has been struck down by one federal court and is being challenged in others. As a result, significant questions remain concerning what the Act and the regulations mean.

**How Are Out-of-Network Payment Rates Determined Under the Act and its Implementing Regulations?**

The Act requires Plans to make a total payment directly to the provider of "the amount by which the out-of-network rate…for such services exceeds the cost-sharing amount…." 42 U.S.C. 300gg-111(a)(1)(C)(iv). The initial payment must be made within 30 days. 42 U.S.C.300gg-111(a)(1)(c)(iv)(I). If Plans and providers do not agree on the out-of-network payment, the Act establishes an independent dispute resolution ("IDR") process. 42 U.S.C. 300gg-111(c). The first step is an initial negotiation period of 30 days. If these negotiations fail to achieve an agreement on the rate, each party is required to submit an offer to the designated IDR entity in a baseball style arbitration where the IDR entity picks one of the two offers. 42 U.S.C. 300gg-111(c)(5)(A)(i).

The Act did not establish a benchmark for the IDR entity to determine out-of-network payment rates, but rather set out "considerations in determination." The considerations included the "qualifying payment amount" or "QPA," which are in the median in-network contract rate for the service in the same geographic region, as well as information in the "additional circumstances" clause. 42 U.S.C. 300gg-111(c)(5)(C)(i). These additional circumstances are: the level of training, experience, and quantity and outcomes measurements of the provider or facility; the market share of the non-participating provider or facility or that of the plan or issuer in the geographic region; the acuity of the patient or the complexity of the treatment; the teaching status, case mix, and scope of services of the non-participating facility; and a demonstration of good faith efforts (or lack thereof) of the provider and plan or issuer to enter into a network agreement. 42 U.S.C. 300gg-111(c)(5)(C)(ii). The IDR entity is specifically prohibited from considering usual and customary charges or amounts paid by public payers such as Medicare in determining out-of-network rates. 42 U.S.C. 300gg-111 (c)(5)(D.)

The Departments of Health and Human Services, Labor, and the Treasury issued two sets of interim final rules under the Act governing, *inter alia*, out-of-network payment rates. Part I established how the QPA would be determined, and generally followed the Act's provisions. 86 Fed. Reg., No. 131 (July 13, 2021). Part II established the standards to be used by IDR entities. 86 Fed. Reg., No. 192 (October 7,

2021). Even though the Act did not set a benchmark for the IDR entities to use in determining the out-of-network payment rate, the Part II regulations attempted to establish a presumption that the qualifying payment amount – the median contract rate – should be used.

Specifically, the interim final rules directed that:

> The certified IDR entity *must* select the offer closest to the qualifying payment amount unless the certified IDR entity determines that credible information submitted by either party under paragraph (c)(4)(i) clearly demonstrates that the qualifying payment amount is materially different from the appropriate out-of-network rate, or if the offers are equally distant from the qualifying payment amount but in opposing directions. In these cases, the certified IRD entity must select the offer as the out-of-network rate that the certified IDR entity determines best represents the value of the qualified IDR item or services, which could be either offer. 45 C.F.R. 149.510(c)(4)(ii)(A). (emphasis added).

The comments to the rules also indicated that the qualifying payment amount was the presumptive rate: "In selecting the offer, the certified IDR entity *must presume* that the QPA is an appropriate payment amount…." 86 Fed. Reg. 55995 (October 7, 2021) (emphasis added). Elsewhere, the comments state:

> …the certified IDR entity must begin with the presumption that the QPA is the appropriate out-of-network rate for the qualified IDR item or service under consideration. Therefore, in determining which offer to select, these interim final rules provide that the certified IDR entity must select the offer closest to the QPA, unless credible information presented by the parties rebuts that presumption and clearly demonstrates the QPA is materially different from the appropriate out-of-network rate.
>
> *Id*. at 55996.

**How has the ongoing litigation changed the rules?**

The provisions of the interim final rules seeking to establish the median contract rate as the presumptive out-of-network payment rate – which would essentially eliminate the additional considerations taken into account by the Act – have been challenged by providers and provider advocacy organizations, including the American Medical Association, the American Hospital Association, and the Georgia College of Emergency Physicians, in several lawsuits. The first court to rule on the merits was the United States District Court for the Eastern District of Texas, which struck down the challenged rules on February 23, 2022 in a lawsuit brought by the Texas Medical Association ("TMA") and one of its physician members.

TMA and its physician member had challenged the rules as inconsistent with the Act. The Court agreed:

> Here, the Act is unambiguous. The Act provides that arbitrators deciding which offer to select 'shall consider…the qualifying payment amounts…and… information on any circumstance described in [the clause listing all of the factors to be considered.]'
>
> *****
>
> Because the word 'shall' usually connotes a requirement, the Act plainly requires arbitrators to consider all the specified information in determining which offer to select. Nothing in the Act, moreover instructs arbitrators to weigh any one factor or circumstance more heavily than the others…And here, the Act nowhere states that the QPA is the 'primary' or 'most important' factor… Nor does the Act impose a 'rebuttable presumption.' (internal quotations and citations omitted).

*Texas Medical Association et al. v. U.S. Dept. of HHS*, 6:21-cv-425, 2022 WL 542879 at *7 (E.D. Tex. Feb. 23, 2022.) The Court also held that the government's failure to use the notice and comment requirements provided for in the Administrative Procedure Act constituted an independent reason to strike down the challenged rules and that the plaintiffs had standing to challenge the rules. Lastly, the Court considered the appropriate remedy and determined that it was to vacate the challenged rules because "the Rule conflicts with the unambiguous terms of the Act in several key respects. This means that there is nothing

the Departments can do on remand to rehabilitate or justify the challenged portions of the Rule as written." Id. at 14.

The government appealed the ruling to the Fifth Circuit Court of Appeals, but also filed an unopposed motion to stay appellate proceedings pending further rulemaking. On May 3, 2022, the Fifth Circuit granted the stay and required the parties to file status reports every 60 days. A case brought by the American Society of Anesthesiologists and two other medical specialty societies in the U.S. District Court for the Northern District of Illinois challenging the same rule provisions challenged by the TMA has likewise been stayed until July 7, 2022. And, the case brought by the Georgia College of Emergency Physicians in the Northern District of Georgia has been stayed until June 16, 2022.

Notwithstanding the *TMA v. HHS* decision, the Act remains in effect, meaning that its provisions protecting patients from surprise medical bills when treated for an emergency condition or by an out-of-network provider in an in-network facility continue to apply. The mechanisms of the IDR process themselves were not challenged and likewise remain in effect. On February 28, 2022, CMS issued a memorandum stating that, effective immediately, it was withdrawing the guidance documents implementing the vacated rules and that it would be revising these documents in conformance with the Court's order. In pleadings seeking stays in the various judicial actions, the government has indicated that it intends to issue final rules in early summer, 2022, which would supersede the portions of the interim final rules struck down by the Court in *TMA v. HHS*. Therefore, the critical issue of how out-of-network payment rates will be determined in the IDR process going forward remains uncertain.

**Deborah Winegard** is Of Counsel with Whatley Kallas, LLP, where she focuses her practice on healthcare litigation and arbitration, primarily representing physicians, hospitals, and other healthcare providers in reimbursement disputes and antitrust litigation against health insurers. Winegard also represents medical societies and organizations advocating for provider interests with payers and governmental entities.

Her prior experience includes serving as the General Counsel and Director of Third Party Payer Advocacy for the Medical Association of Georgia, as General Counsel and Senior Vice President for the California Medical Association, as Facilitator for several of the MDL managed care settlements, as Law & Government Affairs Vice President for four states for AT&T, and as an Associate on King & Spalding's Healthcare Team.

Winegard graduated magna cum laude with a B.A. in Politics from Wake Forest University in 1979, where she was elected to Phi Beta Kappa. She earned her J.D. with honors from George Washington University in 1982.

She currently serves as a member of the Board of Governors and the Executive Committee, and as Chair of the Audit Committee for LifeLink Foundation and as Secretary of the American Society of Medical Association Counsel (ASMAC). She has previously held leadership positions with the Health Law Section of the State Bar of Georgia, the Georgia Association for Women Lawyers, and the National Kidney Foundation of Georgia.

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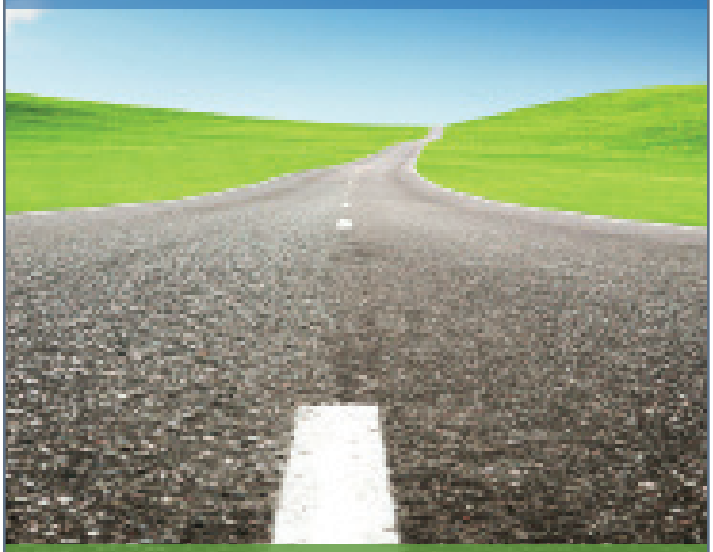

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# Save the Date - October 28

Advanced Health Law Seminar

Please save the date for the Health Law Section's annual Advanced Health Law Seminar and Annual Meeting on Friday, Oct. 28 in Atlanta. We will be back in person this year and can't wait to see you there!