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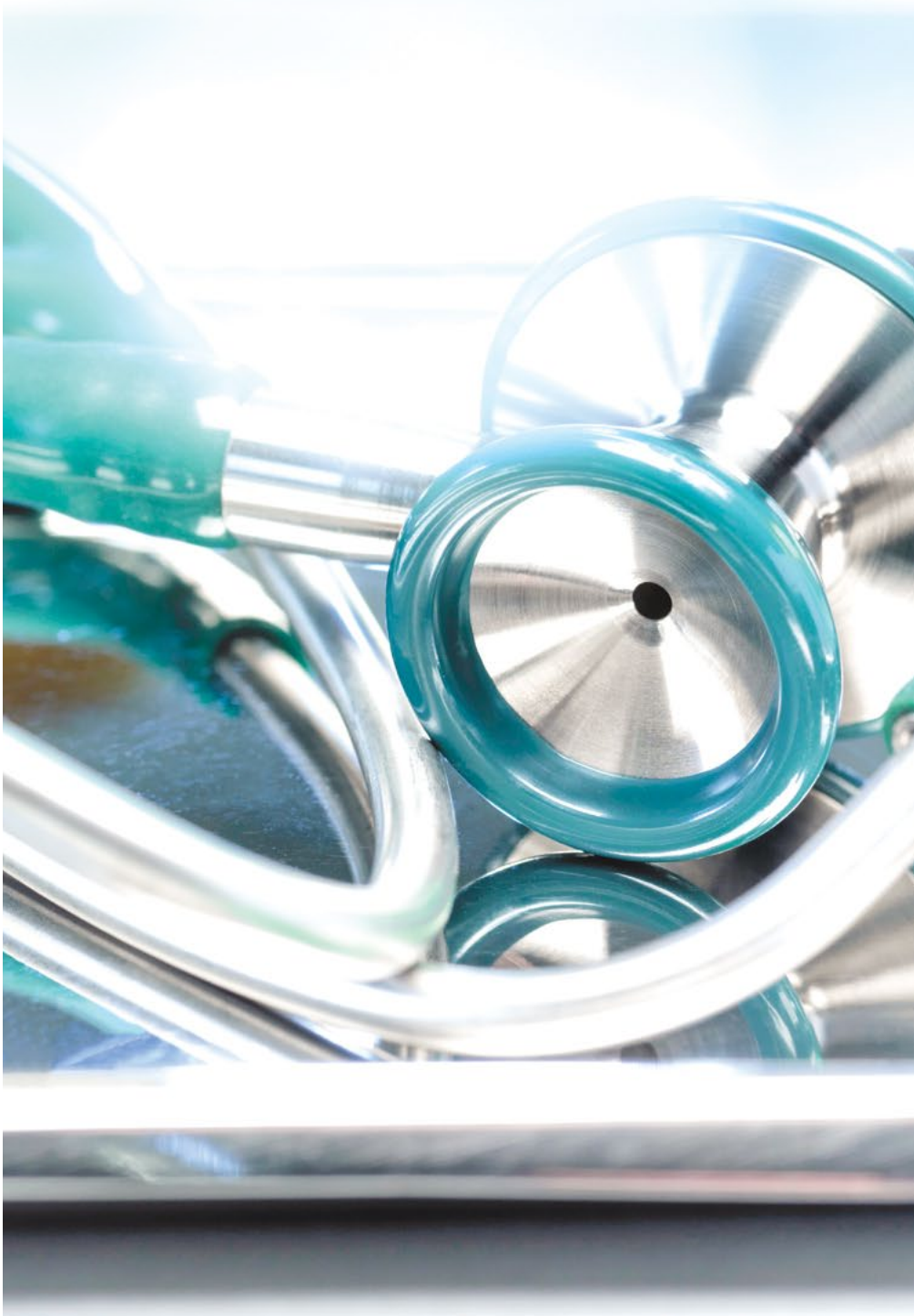

EXECUTIVE MESSAGE

Dear Policyholders,

My career at MLMIC Insurance Company has brought me the privilege of managing malpractice claims, representing practitioners in lawsuits, and now helping healthcare providers and facilities recognize and manage risk. It is my goal to employ MLMIC's unparalleled data, experience, and resources, including relationships with our esteemed policyholders, toward improving patient outcomes and enhancing the defensibility of malpractice claims.

We at *The Scope* endeavor to stay current with the ever-changing landscape of medicine. Developments in technology that revolutionize the way we communicate and the practice of medicine itself impact both the tools of diagnosis and treatment and our understanding of the body's response to injury and disease. As if this was not enough to keep track of, healthcare practitioners and organizations also face changes in the law, the **litigation environment**, and society that determine the expectations and standards to which healthcare providers are held.

In this volume, *The Scope* addresses drug shortages, an ongoing and multifaceted issue for healthcare providers that was most recently exacerbated by COVID. If not managed properly, these drug shortages may directly affect the ability of practitioners to provide patients with effective care, a situation that often leads to claims of malpractice.

Liability issues involving documentation, patient handoffs, the communication of test results, medication errors, and other familiar loss drivers all remain and will continue to be addressed on these pages. But we recognize the very different perspectives that physicians and all other providers enjoy and encourage you to share suggestions borne out of your experience for future topics in *The Scope*.

Please do not hesitate to contact me directly at any time via email, or, better yet, give me a call.

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Taking Action To Address Drug Shortages

The current resource challenges facing healthcare organizations are unprecedented. Issues related to limited resources, including drugs, supplies, and labor, impact overall costs, access to products and services, and, ultimately, patient health outcomes. As a long-standing problem for healthcare providers, our focus in this article will be drug shortages, which can have a negative impact on appropriate therapy regimes and access to needed surgical procedures and also may contribute to medication-related errors and poor patient outcomes.

History

While drug shortages have been a systemic problem for over 20 years, they have become a recent hot topic for patient safety. In 2013, the FDA published its first annual drug shortages report following the enactment of the **Food and Drug Administration Safety and Innovation Act (FDASIA)**, which effectively requires an annual report to Congress on drug shortages.

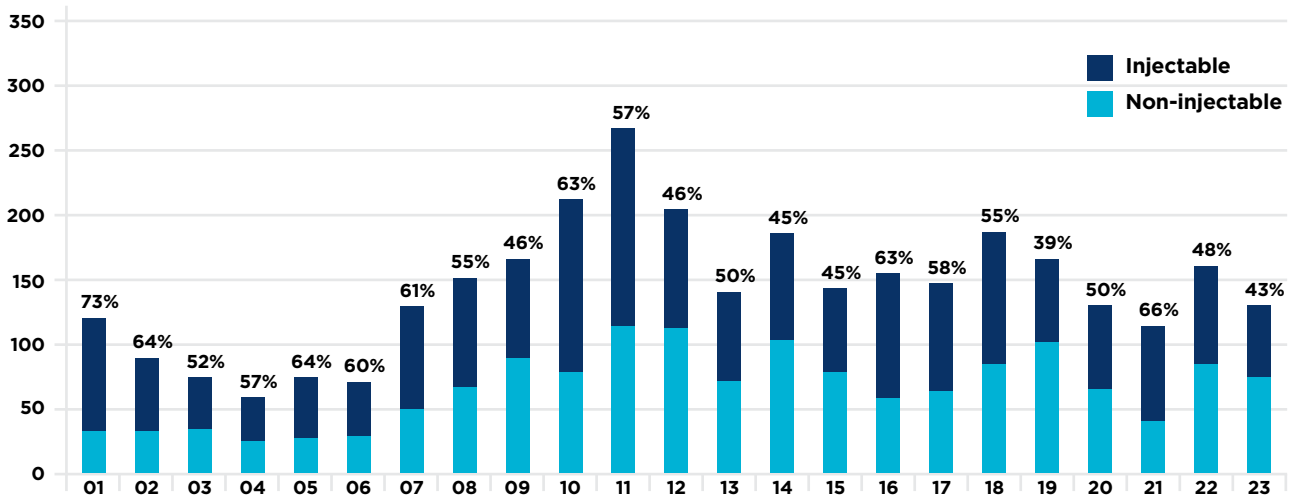
Concerns related to drug and drug product shortages continue: a post on August 18, 2023, titled **Reforms Needed to Alleviate Persistent Drug Shortages**, notes that "the AMA Council on Science and Public Health (CSAPH) is charged with evaluating the factors driving national drug shortages and reporting on progress toward solutions..." The Council's 2022 report on this subject found that, while the number of new drug shortages has trended downward in recent years, the overall number of active drug shortages has remained relatively steady, suggesting that individual shortages are taking more time to resolve.

Unfortunately, a surge in new drug shortages in 2023, combined with the complexity of resolving even a single drug shortage, has resulted in severe stress to the supply chain. **The University of Utah Drug Information Service**, which has tracked drug shortages since 2001, reported that active drug shortages in 2023 were at their highest level in a decade. Its data on real-time shortages are posted regularly on a **website** hosted by the **American Society of Health-System Pharmacists** (ASHP), the largest professional association of pharmacists in support of safe medication practices. The five classes of drugs most frequently in short supply are central nervous system drugs, fluids and electrolytes, antimicrobials, chemotherapies, and hormones."[1]

> **The University of Utah Drug Information Service, which has tracked drug shortages since 2001, reported that active drug shortages in 2023 were at their highest level in a decade.**

National Drug Shortages
New Shortages by Year

January 2001 to September 30, 2023, % Injectable



Note: Each column represents the number of new shortages identified during that year.
University of Utah Drug Information Service
Contact: **Erin.Fox@hsc.utah.edu**, @foxinr for more information.

1 **Reforms Needed to Alleviate Persistent Drug Shortages**. August 18, 2023. By **Jesse M. Ehrenfeld, MD, MPH, President, AMA.**

As of December 28, 2023, **ASHP's website** listed 248 items on the drug shortage list. In a recent MLMIC-moderated panel discussion at the **Association for Healthcare Risk Management of New York's** Fall Conference, one of the panelists stated that her facility's pharmacist mentioned that he had not seen shortages like we are currently experiencing in the last 20 years.

Factors Contributing to Drug Shortages

Pharmaceutical production and distribution is a complex, worldwide system that faces many variables for supply volume. Given these variables, to solely describe drug shortages as supply not meeting demand would be an oversimplification. All areas along the vast continuum of the pharmaceutical supply chain have ample opportunity to contribute to the risk of supply imperfections, reductions, production losses, or distribution delays. One or more of these aspects of supply can impact drugs and drug products reaching the patient. Some examples include:

- Production of raw materials
- Technical and quality issues in the manufacturing systems
- New or modified regulation(s)
- Distribution processes
- Vendors and/or group purchasing organizations
- Healthcare organizations' procurement practices
- Unique attributes of the drug product market, such as the specific challenges of the generic drug sector

> **Given these variables, to solely describe drug shortages as supply not meeting demand would be an oversimplification.**

Each of these areas offer potential complications with product availability and quality, production capacity (including labor force availability), distribution, and business decision-making (e.g., budget constraints), which can be exacerbated by natural disasters or other public health emergencies, such as the recent coronavirus pandemic.

As we will note later, being aware of the the potential for shortages and being proactive in assessments are key to effective medication management programs. Assisting in that preemptive approach is the 2012 **FDASIA** requirement that manufacturers notify the **FDA** of production changes for some drugs and biologicals. The elements to be reported include interruptions or the permanent discontinuation of drugs or biologicals, any of the active pharmaceutical ingredients necessary, and the reason for the interruption. The notification to the FDA should occur 6 months prior to changes or as soon as possible if less than 6 months. This requirement was updated by the **Coronavirus Aid, Relief, and Economic Security Act Act** in 2020 to further mitigate the effects of shortages.

Concerns and Risks for Patient Safety

Not only do providers and their practices and facilities need to be concerned with disruptions to the operational workflows and administrative burdens when planning for current or anticipated drug shortages, the potential negative impacts related to clinical patient safety should be at the forefront. It is well known that patient safety and medication management initiatives are directly related, and changes to medication management processes, from procurement to administration, can increase medication error rates.

In October of 2023, **ECRI**, a patient safety organization, and the **Institute for Safe Medication Practices**, both associates in patient safety, announced information from a survey on the supply shortages and their impact on harm to patients. As noted in the report, "most respondents reported that shortages have compromised patient care, with half saying shortages have delayed patient treatments and one-third reporting they were unable to provide patients with optimally recommended drugs or treatments. A quarter of respondents said they were aware of at least one error related to a drug, supply, or device shortage."[2]

Additionally, changes in available drug substitutes may impact treatment routines by creating delays or complete interruptions in planned care; making errors in instructions to patients or caregivers more likely; and making prescribing errors more frequent as prescribers are forced to use dosing parameters they are not accustomed to.

2 **Medication, Supply, Equipment Shortages are Harming Patients - New Survey Reveals Shortages are Negatively Affecting Patient Care, Causing Harm.** ECRI, October 13, 2023.

In addition to process risks, clinical risks related to shortages and alternative therapies must always be considered. Much uncertainty and the potential for liability concerns come with choosing an alternate medication regime. Is there an alternative option available? Will the new therapy be as effective and meet the current standards of care? Will patients be able to tolerate the available substitution drug? These issues may not only affect the care provided but may also have a tremendous impact on the patient's overall mental well-being, particularly if life-saving treatment is at stake.

> **Much uncertainty and the potential for liability concerns come with choosing an alternate medication regime.**

Although not directly clinical, the potential negative impacts on clinical treatment plans due to the possibility of a payor not covering the costs of available alternative therapies; the ethical dilemmas and emotional struggles created for patients, their families, and staff stemming from distribution or rationing parameters; and issues surrounding the informed consent (e.g., drug alternatives now being considered may warrant an update or a totally new consent process and form) should be concerning.

Strategies for Managing Drug Shortages

On a national level, both the FDA and AMA are leading supporters in reducing the negative effects drug shortages have on patient care through proactive reporting requirements, exploring options to expand investment in production capacity, early notification of impending shortages, ongoing regulatory review, and analysis of contracting practices related to organizations in competition (e.g., GPOs). A November 14, 2023, article in *Medical Economics*, **AMA Pushes for Action on Drug Shortages**, is calling the shortage of drugs a "growing public health crisis."[3]

Even with their continuous efforts to find longer-term solutions, healthcare organizations must be actively vigilant and prepared by establishing a well-defined plan to inform their management of impending or actual disruptions in the drug or drug product supply chain. It is not "if" but "when" the next shortage will occur.

As recent as December 31, 2023, an article titled **Lessons From The Chemotherapy Shortages: Invest in Generics**, authored by Elenora Teplinsky, M.D., a medical oncologist, reflected on the 2023 shortages of chemotherapy agents and the difficulties in managing lifesaving therapy regimes for many cancer patients. She, too, indicated the need for the early identification of potential/imminent shortages, clear paths to address actual shortages, and improvements in production and pricing for the generic drug sectors.

What COVID Taught Us

As we have heard multiple times, if we've learned anything from the COVID pandemic, it is that we have to be prepared for the next one. The variables are complicated, with many along the drug and drug product supply chain continuum requiring proactive and ongoing attention and investment, both financial and from a human capital perspective.

Creating a management plan and structure involving a multidisciplinary team with decision-making authority is critical to an organization's success in navigating the challenges created by interruptions and shortages in the supply chain. Preemptively addressing the following areas and proactively monitoring for impending shortages are essential as ongoing organizational assessments could identify actions to be taken prior to the formal announcement of a shortage, which could then reduce the stress on an already burdened system.

Oversight

A multidisciplinary team reviewing the impact of drug shortages should have decision-making capabilities from:

- **Purchasing and Finance** — to leverage relationships with vendors and also have the liquidity to act quickly when necessary to secure resources as they become available.
- **Pharmacy Processes** — to secure the appropriate physical space and environmental requirements related to storage and preparation needs.
- **Information Technology (IT) and Security** — to manage data collection and monitoring that includes medication error rates before, during, and after shortage activities. Information gained from

3 AMA Pushes for Action on Drug Shortages. November 14, 2023. By Jeffrey Bendix, Medical Economics.

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AM BEST®

AM Best Update

MLMIC Insurance Company is pleased to announce that **AM Best**, the preeminent credit rating agency for insurance companies, has again "affirmed MLMIC's Financial Strength Rating of A+ (Superior) and its Long-Term Issuer Credit Rating of "aa-" (Superior)."

A+ Superior

Per AM Best, "these ratings reflect MLMIC's balance sheet strength, which AM Best assesses as strongest, as well as its adequate operating performance, limited business profile, and appropriate enterprise risk management."

For more information:

AM Best Press Release | MLMIC Acknowledgement

CASE STUDY:

A Wrongful Birth Case

In this case, a 25-year-old female alleged that, during her pregnancy, she was not fully informed that her infant would suffer birth defects, and, had she known, she would have opted to terminate the pregnancy.

Treatment

The patient was initially seen in the emergency department (ED) of a MLMIC-insured hospital with complaints of discomfort when urinating and a potential pregnancy as a home test had been positive. A serum pregnancy test was positive, but a transabdominal sonogram did not detect the pregnancy. A pelvic exam and transvaginal ultrasound were offered, but the patient refused. She was diagnosed with a urinary tract infection and "early pregnancy" and advised to follow up with her primary medical physician as well as an obstetrician.

> A serum pregnancy test was positive, but a transabdominal sonogram did not detect the pregnancy.

Two months later, the patient was seen by a MLMIC-insured OB-GYN for a confirmed pregnancy and was referred for an ultrasound. The ultrasound was performed and interpreted by a MLMIC-insured radiologist, who confirmed a gestational age of 13 weeks and 4 days. There was no mention of an abnormality on the report or discussions with the mother reporting any issues with the fetus, including an omphalocele.

The following day, the patient presented to the hospital's ED complaining of heavy bleeding the previous day. She was seen by a MLMIC-insured nurse practitioner, and the physical and pelvic exams were normal. An ultrasound was performed, and the report by another MLMIC-insured radiologist stated, "single intrauterine gestation with estimated gestational age of 13 weeks and 2 days with a fetal heart [rate] of 145 bpm" and "an ovoid soft tissue mass-like structure along the anterior abdominal wall, possibly an omphalocele versus physiologic herniation."

This was the first indication of an abnormality with the fetus. However, on the patient's next visit to the OB-GYN, while there was no mention of

this negative ultrasound or any discussion with the patient, the patient was referred for a Level 2 sonogram. The reason stated for this study was "presumed omphalocele on prior exam."

> This was the first indication of an abnormality with the fetus.

This ultrasound was not done until 4 weeks later at a gestational age between 19 and 20 weeks. It was interpreted by another MLMIC-insured radiologist, who confirmed the omphalocele along with a left-sided diaphragmatic hernia. Close clinical observation and consultation were suggested. However, although the patient was seen by her obstetrician on two more occasions, the ultrasound findings were not conveyed to her on either visit.

At 27 weeks and 1 day, the patient requested a 3D ultrasound as a keepsake of her pregnancy. She was told by the radiology office at that point that this could not be done, and they advised her to contact her OB-GYN. She was seen by this doctor that day, and the issues with the fetus were discussed. At that point, her physician referred her to a perinatology office.

The patient was seen at the perinatology center at 29 weeks, and a Level 2 ultrasound confirmed "the presence of a large omphalocele with a portion of the fetal liver, diaphragmatic hernia and significant displacement of fetal heart and stomach." Chromosomal studies were normal, but the patient was advised of the complexity of the situation and that the infant would require surgery.

The pregnancy continued to term, and the infant was delivered via C-section at 39 weeks. The infant was transferred to the NICU at another hospital and remained there for 7 months, requiring multiple surgeries and procedures including three hernia repair surgeries, the placement of a gastrostomy tube, and surgery to correct gastroesophageal reflux disease. The infant suffered significant developmental and global delays, asthma, and respiratory distress and is on a host of medications. The infant uses oxygen and has had multiple hospitalizations, in addition to needing a G-tube for feedings. Gastroenterology and nutritionists were recommended, though the family has been lax in this department. The infant requires occupational, physical, and speech therapy as well as special education.

Expert Opinions

This case was reviewed by specialists in obstetrics and gynecology, radiology, emergency medicine, and pediatrics. Their consensus was that an OB-GYN should follow up on the results of all ordered sonograms, discuss the results with the patient, and provide counsel accordingly. This was clearly necessary in this case due to the serious nature of the fetal abnormality.

> Their consensus was that an OB-GYN should follow up on the results of all ordered sonograms, discuss the results with the patient, and provide counsel accordingly.

The radiology and ED experts agreed that, while it is the referring physician's responsibility to advise the patient of all sonogram findings, they suggested that the radiologists should have communicated with the OB-GYN to ensure that the reports had been received, especially due to the findings.

The pediatric reviewer opined that the infant suffered from congenital defects and no treatment would have prevented the outcome. However, the mother was not counseled appropriately regarding the nature of the abnormalities and was denied the opportunity to terminate the pregnancy should this have been her choice.

Lawsuit

The mother brought an action against multiple MLMIC insured physicians to recover expenses related to childcare and alleging failure to provide appropriate ultrasound results that confirmed possible birth defects. She alleged that had she been provided with this information, she would have sought a termination of the pregnancy to avoid the expense of caring for a child with multiple deficits. The mother sought to recover expenses incurred to care for the infant's special needs until the age of 21 and claimed that the child was

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MSSNY and MLMIC Announce an

Exclusive 10% Policy Premium Discount

for Qualifying Members of MSSNY

The Medical Society of the State of New York (MSSNY) and MLMIC Insurance Company (MLMIC) are pleased to introduce a new, exclusive savings program that will give qualifying members of MSSNY a 10% discount on their MLMIC medical professional liability premiums.

MEDICAL SOCIETY OF THE STATE OF NEW YORK
ORGANIZED 1807

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This new MSSNY member offering joins MLMIC's growing roster of **Preferred Savings Programs**, which now includes a dozen options, enabling more qualifying New York physicians to get the highest-quality liability insurance at an even lower cost.

"MSSNY constantly strives to bring valuable services and benefits to its members. We are proud to partner with MLMIC on this program and other initiatives," said Dr. Paul A. Pipia, MSSNY President.

Born out of the auspices of MSSNY in 1975 during the malpractice crisis, MLMIC has continually been the trusted and exclusive medical professional liability partner of MSSNY. This new program will bring a MLMIC premium discount opportunity to MSSNY's network of approximately 20,000 member physicians.

"MSSNY and MLMIC's collaboration spans nearly 5 decades. We truly understand healthcare in New York and are proud of our many efforts. This program is another example of our commitment to New York physicians," said Dr. John Lombardo, Chief Medical Officer of MLMIC.

MSSNY members who are MLMIC policyholders may also be able to take advantage of **additional discounts of up to 30% in total savings** on MLMIC medical professional liability insurance premiums.

Click **here** to learn more about this new discount opportunity for MSSNY members.

Additional discount programs that are available include:

- **Up to 12%** for qualified physicians and surgeons with no open or closed claims.
- **5% savings** when you complete a New York State-qualified Risk Management program.
- **5% savings** for individual physician policyholders who waive consent to settle a claim.
- **2% premium credit** for prompt payment of the full annual premium within 30 days of receipt of the invoice.

If you have any questions about the new MSSNY 10% discount program or any other MLMIC discounts, you can call **(855) 300-6935** or submit a request for more information **here**.

Case Study: A Wrongful Birth Case — continued

disfigured (abdomen) and suffered from health issues, including omphalocele, a congenital hernia, hypertension, and chronic respiratory issues.

> **She alleged that had she been provided with this information, she would have sought a termination of the pregnancy to avoid the expense of caring for a child with multiple deficits.**

During the patient's deposition, she was questioned as to whether she would have undergone an abortion had she been aware of the infant's condition when termination of the pregnancy was a viable option. She testified that "she did not know if she would have sought an abortion." The patient was the recipient of social services and testified that, other than formula, she did not incur out-of-pocket expenses to care for the child, and, at most, her total expenditures were $1,000. The infant received Social Security Disability.

Although the plaintiff initially denied being pregnant during her deposition, it was clear that she was pregnant and was not forthcoming during her testimony. This tarnished her credibility.

The defense counsel felt that the damages in this case were not significant due to the testimony regarding the plaintiff's minimal expenses and reasoned the chances of recovering on this matter would be questionable. As such, they were able to successfully obtain stipulations of discontinuance for all of the radiology defendants. A motion for summary judgment was made on behalf of the remaining physicians, which was granted. The plaintiff's counsel did not seek an appeal, and our files were closed with no indemnity payments made on behalf of our Policyholders.

A Legal and Risk Management Analysis

In this situation, the favorable result for the defendants was not a victory to be celebrated. Although there was a fortunate legal outcome, there were clear deviations in the treatment that resulted in irreparable harm to the plaintiff. The failure to provide this patient with the test results revealing the fetal abnormality in a timely manner led to serious consequences.

First, the OB-GYN failed to follow up on the test results of the sonograms ordered. This resulted in a failure to discuss and appropriately counsel the patient about the crucial findings of the abnormality and allow the patient to make an informed decision about the progression of her pregnancy. It is the responsibility of the ordering physician to promptly follow up and review the results of diagnostic tests. This is critical for patient safety, and the failure to do so can lead to a delayed or missed diagnosis, as it did in the case at hand.

Medical offices need to have an effective test result tracking system that will efficiently follow up on test results to guarantee that they are received. They should also have communication policies and procedures that will ensure patients obtain these results in a timely manner. This communication is vital. Patients should know the results of any medical tests they have undertaken, especially those that have a significant finding.

Second, other than solely relying on the written report, the radiologists should have reported the abnormal test results to the ordering physician. As seen in this matter, the breakdown of communication and the failure to report the vital abnormal results directly to the ordering physician resulted in a delay to inform and a serious detrimental outcome for the patient.

Providing timely and accurate information on test results is essential for safe and effective healthcare. In this issue of *The Scope — Medical Edition* is a **list of tips** that should help ensure the proper communication of this information.

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The Grieving Families Act — Defeated, but not Finished

One of MLMIC Insurance Company's many value-added services is providing legislative updates to our policyholders. By now, you have probably heard that Governor Hochul vetoed a second version of the commonly called "Grieving Families Act" (GFA) on December 29, 2023. This bill would have dramatically increased medical professional liability costs in New York State and imposed this increase by adding non-economic damages (damages that are notoriously difficult for juries to quantify) in the form of "grief or anguish" monetary awards for family members whose loved one was found in a lawsuit to have suffered a wrongful death through the negligence of the defendant. Well-respected actuarial firm Millman conducted a study that found the addition of "grief or anguish" damages would increase overall medical professional liability premiums in New York by over 30%.

MLMIC collaborated with its physician, dental, and hospital policyholders, as well as the numerous organizations these policyholders are members of, to advocate against the GFA. It is a tribute to all of our policyholders and MLMIC-endorsed partner medical organizations, including the Medical Society of the State of New York (MSSNY) and the Healthcare Association of New York State (HANYS), that this collaborative advocacy led to Governor Hochul's second veto of the GFA legislation. The letters, calls, public rallies, and op-ed articles submitted by New York medical providers and organizations were truly powerful both in volume and substance. MLMIC is deeply appreciative of all the hard work performed by these individuals and groups.

In a quick turnaround from the December veto, this same bill was reintroduced in the senate on February 5, with legislators again looking to expand exposure in these cases. Rest assured, MLMIC will continue to work with all of our policyholders, MSSNY, HANYS, all of our endorsed partners, distribution partners, and other MLMIC stakeholders to advocate against any new GFA bill that still contains the costly addition of non-economic damages.

Thank you for your continued support of MLMIC's efforts to advocate on your behalf in opposing any new bill that would expand liability for New York State medical professionals.

Marc Craw is an attorney with the General Counsel Office of MLMIC Insurance Company.

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Taking Action To Address Drug Shortages — continued

data analysis can be helpful in anticipating future requirements or addressing issues that may arise during a shortage.

- **Risk Management** — to address impacts on patient safety.
- **Nursing** — to provide insight into workflow, staffing, and training needs.
- **Communications & Education** — to expedite cross-functional training plans and provide all stakeholders with contemporaneous situational updates related to the shortage and process changes made in response to the shortage.

Distribution

Drug shortages that require decisions related to rationing limited pharmaceutical resources may necessitate a collaborative group specifically focused on managing drug and drug product distribution as well as determining the clinical stratification parameters needed to prioritize distribution. These decisions are complicated and, in many instances, emotionally charged.

The group established should be multidisciplinary, with delegates from pharmacy, nursing, social services/care management, medical expertise, patient advocates, ethics, human resources, and legal/risk management, and other disciplines, if necessary.

Communication and Documentation

Effective communication skills for both internal and external conversations related to drug shortages are a critical part of setting and managing realistic expectations and fostering a culture of collaboration and will assist in leveraging existing relationships. Internally, sharing information with practitioners may alleviate stress by reducing the number of unknowns related to shortage details, such as current inventory status and active substitutions or alternative treatments, what the distribution priorities and rationing protocols are, and any cancellations of or changes to routine operations.

Outside of the organization, plans to communicate with patients and their families, including conversations about difficult situations, must be considered, in addition to how an organization will respond to the local community or media with an appropriate spokesperson.

As always, detailed documentation related to patient care, treatment, and services, as well as other processes related to business interruption, will be necessary to accurately reflect and "tell the story" in a detailed and accurate manner, regardless of the subject matter.

How the patients respond to alternate therapies, as well as details of the informed consent discussion resulting in the chosen care plan, must be reflected in the medical record. Dates and details of decisions related to changes in services, protocol adjustments, or any new clinical practices implemented should be archived for future reference, accompanied by evidence of staff education related to these changes. Tracking the specifics of actions is an important part of accountability and responsibility and will always be your best defense in a legal action.

> **How the patients respond to alternate therapies, as well as details of the informed consent discussion resulting in the chosen care plan, must be reflected in the medical record.**

Looking Ahead

While large-scale efforts to support changes to drug manufacturing, supply chain processes, and issues with the generic drug market are in progress, there are no real solutions in the immediate future. With that, we must enhance our organizational framework, allowing for proactive monitoring, and foster nimble, creative, and collaborative decision-making related to our pharmaceutical products and supplies.

Thorough documentation of attempts to address drug shortages, as well as communication to patients and staff of these efforts, will be essential should a patient experience an untoward outcome related to care due to the shortage of essential drugs.

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TIP #15
Communicating and Following Up on Critical Test Results

The Risk

The communication of test results is an important part of providing care and may involve various healthcare professionals. Test results may be overlooked, lost, scanned into the wrong record, or otherwise misplaced.

Abnormal test results requiring follow-up present an additional risk if they are not received, reviewed, or communicated to the patient. This may result in missed or delayed diagnoses, patient injuries, and subsequent claims of malpractice.

If a physician orders a test, he or she is responsible for ensuring that the results have been received and reviewed. Physician practices should have policies and procedures in place for the management of test results.

Recommendations:

1. All ordered tests must be documented in the patient's medical record.
2. A process should be in place to confirm and document the receipt of test results. Many electronic health record systems allow practices to efficiently track pending laboratory/diagnostic studies.
3. All incoming laboratory reports and diagnostic tests must be reviewed and authenticated by the provider.
4. The provider must document communication of the test results to the patient. Any recommendations or interventions must also be documented.
5. Providers should have a system in place for the follow-up of pending laboratory/diagnostic test results for their patients who have been discharged from the hospital or ED. Receipt and review of these results should be documented in the patient's medical record. Communication of the results to the patient should also be documented.
6. It is important for physicians to clearly establish who is responsible for follow-up when tests are ordered for a patient by another specialist or consultant.
7. Patients should be advised of all test results, normal or abnormal. This communication should be documented in the medical record.

For more information and guidance, please contact MLMIC's Risk Management Consultants at **(800) 275-6564** or via **email**.

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