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The attorneys at Fager Amsler Keller & Schoppmann, LLP, are available during normal business hours to assist MLMIC insureds with a wide range of legal services, including, but not limited to, advisory opinions concerning healthcare liability issues, liability litigation activities, lecture programs, and consulting services.

Healthcare law, regulations, and practices are continually evolving. The information presented in *The Scope* is accurate when published. Before relying upon the content of an article from *The Scope*, you should always verify that it reflects the most up-to-date information available.

EXECUTIVE MESSAGE

The Meaning in What We Do

We all seek meaning or purpose in what we do. What that meaning or purpose might be differs from person to person. For some, work is simply a means of providing for themselves or their families. For others, it provides funding for other pursuits or interests. My children gave me a plaque that I keep on my desk that says, "I work hard so that my dog can have a better life" (shows what's important to them).

But seriously, for me, it's simple. I find meaning and purpose in the fact that we are the frontline defenders, advocates, and allies for healthcare professionals. Unlike characters from a movie or TV show, healthcare professionals are our true heroes — people who put their health and safety on the line each and every day to care for all of us, our families, and our loved ones. MLMIC is proud to represent them, advocate for them, defend them, and protect them.

Each and every employee of MLMIC plays a part in protecting our policyholders. Our Team approach, in all disciplines, provides Insureds with superior service on their accounts at the best pricing possible. From frontline servicing departments to back-end support departments, MLMIC's knowledgeable and caring staff are there to address the insurance needs of our policyholders every step of the way, so that these hardworking professionals can survive in today's tough healthcare environment.

As individuals, we strive to be the very best at what we do, coming together as a larger, stronger team, in order to increase patient safety, improve outcomes, defeat needless and meritless cases, and drive better pricing and structures for those in healthcare who need it the most.

It is our meaning, our purpose, to protect healthcare professionals and institutions like no other — to provide service like no other. That is who we are. That is MLMIC.

We look forward to continuing to serve the interests of New York's healthcare professionals, like no other, in 2022.

Happy holidays and thank you,

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Fager Amsler Keller & Schoppmann, LLP

Interoperability — Ensuring Technology Works for You

Healthcare organizations have a duty to provide a safe environment for patients. But while patient safety, which includes the safe use of equipment and devices, continues to be a primary focus across the healthcare continuum, increased efficiencies in the delivery of healthcare are also necessary to both maintaining a professional organization's financial stability and continuously improving the patient experience. Technologies like artificial intelligence, 3D printing, robotics, remote monitoring, and nanotechnology seem to be constantly implemented or updated. Employing such technologies, and having them all work together efficiently and safely, creates additional considerations for healthcare organizations.

Technological advances do not come without threats to patient safety, and their implementation and operation require management strategies to mitigate both harm to patients and the resulting professional and general liability claims. Possible dangers can be related to systematic issues such as design flaws, operative failures, and/or user errors such as misuse and employing workarounds. This article will focus on interoperability issues and offer suggestions for leadership and risk managers alike to consider when deploying new technologies.

According to the Healthcare Information Management Systems Society, interoperability is "the ability of different information systems, devices and applications to access, exchange, integrate and cooperatively use data in a coordinated manner, within and across organizational, regional and national boundaries…" Federal mandates such as the Interoperability and Patient Access final rule (CMS-9115-F)(85 FR 25510), which went into effect on June 30, 2020, are expected to boost the exchange of data through new Application Program Interfaces (API) and Fast Healthcare Interoperability Resources (FHIR). While focused on payment data and patients' access to their health information, the final rule is an initiative that begins to address interoperability issues on a more global level.

Whenever technology is involved in healthcare, there is the potential for failures, both systemic and those involving human error. Communication among all forms of technology needs to occur in a seamless manner so that healthcare professionals can have access to all necessary information and can provide appropriate care. Lack of data integrity and poor functionality both present risks to patient safety; if interoperability failures occur, the results can be catastrophic.

> **Lack of data integrity and poor functionality both present risks to patient safety; if interoperability failures occur, the results can be catastrophic.**

The connectivity of the systems and programs used within an organization, as well as those connected to externally, and the accurate transmission of information, both internal and external, to organizations communicating among themselves are vital to patient care and safety. And while healthcare providers usually associate computer/digital technology with interoperability, it is also worth noting that interoperability factors can also apply to other devices within your organization.

Unfortunately, MLMIC Insurance Company has seen an increase in patient safety events that resulted from a lack of interoperability. The following case examples identify some of these risks.

Transmission Errors or Omissions

At one facility, fetal monitor data was not being displayed on the nurses' workstations after the obstetrical data system server was moved off-site. There was no testing on the unit prior to this move. After investigation, it was found that a recent firmware update for wireless access points inadvertently caused some medical devices to lose the ability to operate wirelessly.

At another facility, the transmission of a medical imaging report indicating necessary follow-up was not directed to the appropriate module in the EHR, which created a dangerous delay in diagnosis. Similar events have occurred in which the information was transferred to the wrong patient's record. In addition to the patient safety concerns, these errors in transmission can create privacy issues.

Interfaces

When a pharmacy at a facility updated its medication library, the medication choices in the computerized physician order entry (CPOE) module were not reconciled. The system was not tested before it was implemented with missing and duplicated medication choices and many incorrect dosing parameters. Fatal medication errors occurred before this issue was identified.

> In addition to the patient safety concerns, these errors in transmission can create privacy issues.

Complete Functional Failure of a Device

In one instance, an unknown source of electro-magnetic interference caused the failure of an apnea monitor alarm, resulting in an anoxic event.

Physical Compatibility or Incompatibility

In this instance, a fatal cardiac arrest occurred when the medication intended for epidural administration was given intravenously. The bags of epidural anesthetic and an IV medication looked similar in size and shape, and the same catheter could access both types of bags.

At another facility, a code team arrived to find defibrillator pads that could not be connected to the defibrillator itself, causing a delay in treatment.

> It is imperative each organization create and maintain a robust "technology" program to address issues that can occur across an organization.

The volume and speed of the advancement in technologies essential to healthcare and its rapid evolution are incredible and unlikely to slow down. In addition to the burden of costs associated with adding and maintaining technology, these near-constant developments make maintaining competency and expertise challenging. It is imperative each organization create and maintain a robust "technology" program to address issues that can occur across an organization. Remaining vigilant and exercising proper leadership, expertise, and oversight are critical to ensuring that programs are in place to monitor connectivity and operational flow.

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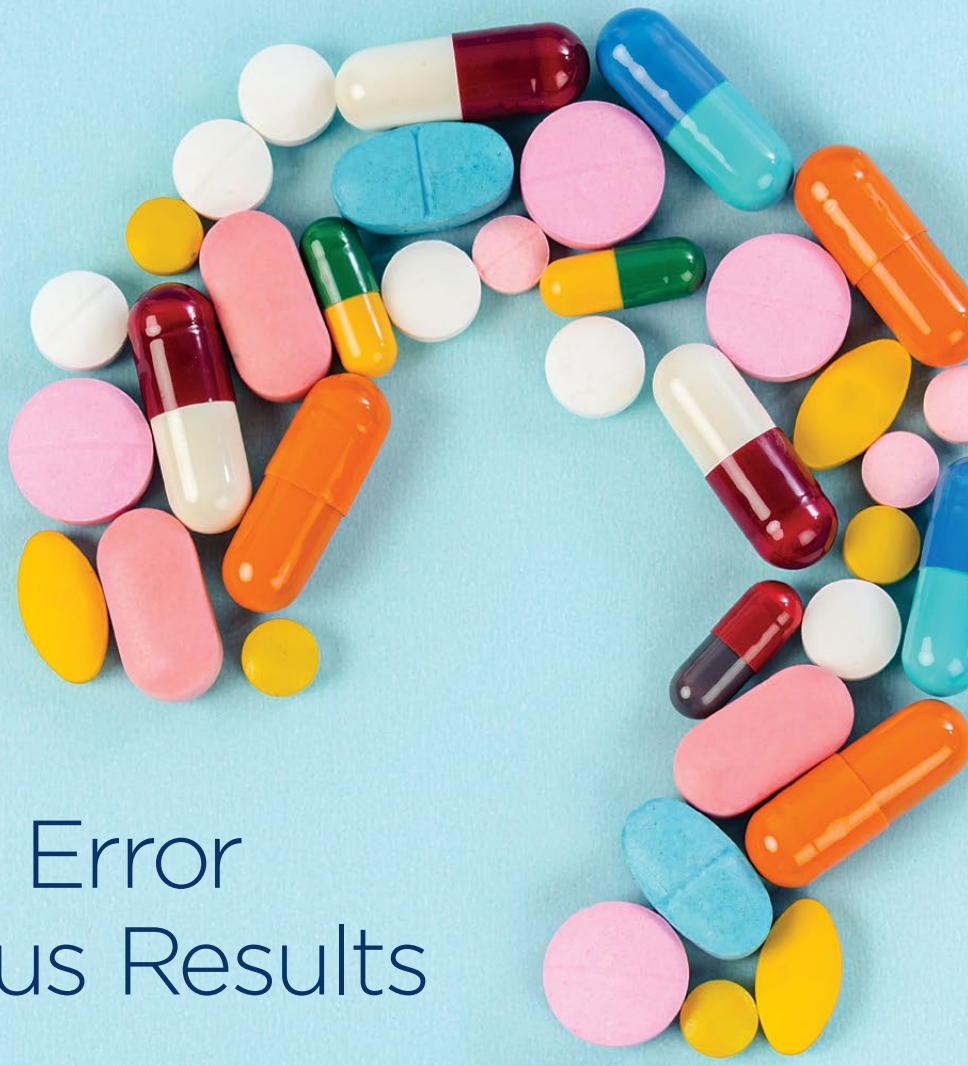

CASE STUDY:

A Medication Error with Disastrous Results

An 83-year-old retired female who was living with her daughter was brought to the emergency department at 11:30 A.M. on July 12, 2010, by her son at the recommendation of her private physician due to complaints of diarrhea and weight loss for several weeks. The triage nurse documented the patient's abdominal pain as zero on a scale of zero to ten, and noted a past medical history of diabetes, phlebitis, vasculitis, atrial fibrillation, cellulitis, scoliosis, osteomyelitis, arthritis, pneumonia, diverticulitis, and TIA.

> **Although it was documented that the patient was on medications, the son did not remember to bring her medication list...**

Although it was documented that the patient was on medications, the son did not remember to bring her medication list, and she could not recall what she had been prescribed. However, she advised the nurse of her allergies to penicillin, sulfa, clindamycin, and scallops. Normal vital signs were exhibited. The patient's private attending physician, a MLMIC-insured internist, met the patient in triage.

The patient was evaluated by a resident who documented melena, chest pain, shortness of breath, nausea, vomiting and abdominal pain, and that, although thin, the patient did not appear to be in any distress. Her abdomen was soft, non-tender and non-distended with no rebound or guarding, and no pulsatile mass or palpable hepatosplenomegaly. The remainder of the exam was normal. The resident's differential diagnosis was dehydration and diarrhea, ruling out colitis, mass, or electrolyte abnormality.

The MLMIC-insured emergency room attending physician saw the patient and noted a three-week history of diarrhea with bowel movement each time she ate, pain to the left side of the abdomen, and weight loss of 3-4 pounds, which were consistent with the resident's findings. He documented a history of diverticular disease, and his differential diagnosis included diverticulitis, colitis, C. difficile, electrolyte abnormality, and dehydration. Laboratory blood work was drawn resulting in BUN 28, creatinine 1.2, PT 122, INR 13, and PTT 64.4. A urinalysis was positive for trace protein and negative for glucose, blood, and leukocyte esterase. Stool tests, including stool for culture, O&P, leukocytes, and C. difficile were cancelled by the resident. The patient was treated with IV fluids, and repeat vital signs taken at 2:18 P.M. were normal.

A CT scan of the abdomen and pelvis with oral and intravenous contrast was ordered. Due to the patient's allergy to scallops, Benadryl and Solu-Medrol were administered with 500 cc bolus of intravenous normal saline followed by a drip at 100 cc per hour for a total of 1,000 cc. The radiologist's impression was bilateral extra renal pelvis versus mild hydronephrosis, worse on right, but present in the previous study and unchanged. Also noted was stool throughout the colon without evidence of obstruction, free air, or significant inflammatory disease. Diverticulosis was noted, but no diverticulitis. At some point subsequent to the CT scan, the patient's daughter arrived in the ER and provided our insured with her mother's medication list. He advised that it would be scanned to her record.

At 4:37 P.M., the ER resident documented that he had discussed the patient's coagulation results with the internist, and a decision had been made to repeat the test. The resident noted that the patient had a left lateral subconjunctival hemorrhage. Repeat studies revealed PT 147.4, INR 15.5, and PTT 57.3. As such, vitamin K 10 mg was given subcutaneously. At 7:01 P.M., the patient was discharged from the ER with a diagnosis of a Coumadin overdose and diverticulosis. She was advised to eat green leafy vegetablesand not take her Coumadin until she spoke to her internist.

On July 16, four days after discharge, the patient was brought by ambulance to the same emergency room with a chief complaint of intermittent diarrhea for two weeks. She had no pain, vomiting, nausea, or bloody stool, but had trouble walking. Her vital signs were normal. She was evaluated by another resident whose exam was negative. Lab work showed BUN 99, creatinine 5.9, PT 16.4, INR 1.7, and PTT 34.7. A urinalysis was positive for protein, blood, and ketones.

A non-contrast CT was done and interpreted by another radiologist, whose impression was colonic diverticulosis without diverticulitis and no intestinal obstruction. An EKG revealed atrial fibrillation with ventricular rate of 100 and non-specific ST-T wave changes. The patient was evaluated by another ED physician and her primary internist and admitted to the ICU with a diagnosis of acute renal failure and lactic acidosis secondary to contrast-induced nephrotoxicity. On July 17, her BUN dropped to 50 and creatinine was 3.2 with lactic acid 12.5. She continued to deteriorate over the next few days, suffering septic shock and multi-organ failure, and expired on July 26, 2010.

> **The patient was evaluated by another ED physician and her primary internist and admitted to the ICU with a diagnosis of acute renal failure and lactic acidosis secondary to contrast-induced nephrotoxicity.**

The decedent's daughter, the executrix of her estate, commenced a lawsuit against the hospital and its ED resident, the patient's internist, and the MLMIC-insured ED attending. The plaintiff alleged that the order of a CT scan with contrast when the patient was on metformin was contraindicated. Upon her discharge, the patient was never advised to discontinue metformin for 48 hours following the CT scan.

Expert reviews were not favorable for our insured and the co-defendants. They concluded that the failure to obtain a complete medication history and the decedent's discharge in light of the abnormal coagulation studies were problematic. The experts further opined that the intravenous contrast in conjunction with the patient's continued use of metformin likely led to the development of acute renal failure.

> **The medication list was scanned into the ED chart on July 12, 2010, but was not signed or dated. The ED physician claimed to have no recollection of this encounter.**

At her deposition, the decedent's daughter testified that she had provided a complete medication list to the ED physician. The medication list was scanned into the ED chart on July 12, 2010, but was not signed or dated. The ED physician claimed to have no recollection of this encounter.

At his deposition, the private attending physician testified that he met the patient in triage. It was noted that he never made any chart entry during the ED visit. He also testified that he was neither asked about the patient's medication history nor advised about the medication list provided by the family. He stated that had he known about the CT scan with contrast, he would have discontinued the metformin following the patient's discharge.

> **The case was considered indefensible and was settled for a total of $350,000...**

The case was considered indefensible and was settled for a total of $350,000 with apportionment of $300,000 to our insured ED physician and $50,000 on behalf of the co-defendant hospital and its resident. The private attending physician was discontinued from this lawsuit.

A Legal and Risk Management Analysis

Medication errors are a major cause of morbidity and mortality. Medication histories are important in preventing prescription errors and preventing harm to the patients. The medical history should include all current prescribed medications, any previous adverse drug reactions, and all over-the-counter medications. Having an accurate medication history helps avoid errors in prescribing, which may lead to the unwanted duplication of drugs, drug interactions, discontinuation of long-term medications, and failure to detect drug-related problems. Unfortunately, these errors are more common on admission to a hospital.

> **The medical history should include all current prescribed medications, any previous adverse drug reactions, and all over-the-counter medications.**

Patients, particularly elderly patients, often are not able to report their drug history accurately. Elderly patients represent a large group of emergency patients. Due to cognitive deficits or due to their physical condition in the emergency room, taking a reliable medical history in this patient group can be difficult. In this case, the patient's failure to provide a complete medication history led to treatment that was contraindicated and ultimately led to acute renal failure and death.

> **However, if the patient was unable to provide the needed information, the nurse should have used other sources...**

The patient had an extensive medical history. Obviously, the patient is the best source for information. However, if the patient was unable to provide the needed information, the nurse should have used other sources, which can include family/caregiver, the patient's medication bottles, the patient's pharmacy, the patient's primary care physician or other physician, or past medical records. In this case, the nurse had two other sources present in the emergency room. The first one was the patient's private attending physician, who physically met the patient in the triage and could have provided a complete prescription history. Another source was the son of the patient who accompanied her to the ER.

The daughter testified that a list of the medications was provided later, after the presentation to the ER. This medication list was scanned into the EHR, but was neither dated nor signed. Unfortunately, there is no indication of who scanned it into the system or any indication that it was ever reviewed by any provider. This is an example of poor documentation. Accurate, legible, and complete documentation can be the best defense against a malpractice claim. In this case, it would have avoided a serious medical complication that led to death. A well-documented chart is one that is made contemporaneously with treatments and/or events, and therefore does not rely on anyone's memory. It is imperative for all providers to ensure that whatever is scanned into the medical records is reviewed and appropriately documented.

> **Accurate, legible, and complete documentation can be the best defense against a malpractice claim.**

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A Legal and Risk Management Analysis *(continued)*

Finally, the hospital improperly discharged the patient, who had abnormal coagulation studies. Premature discharge has the greatest impact on the elderly, causing potentially serious risks to their health. They are older and could have trouble understanding their discharge instructions and/or medication dosing. The hospital must properly stabilize a patient's condition, diagnose and treat a patient, and conduct necessary tests. A premature discharge from a hospital or other care facility can cause as much harm as any other medical error committed by a healthcare professional.

> **The hospital must properly stabilize a patient's condition, diagnose and treat a patient, and conduct necessary tests.**

As this case illustrates, prior to discharge, providers must make sure there is medication reconciliation. The patient's medications must be cross-checked to ensure that no chronic medications were stopped, and that any further treatment and/or new prescriptions are safe and not contraindicated. There must also be proper and complete discharge communication and/or instructions. This involves discussing medication changes, pending tests and studies, and any follow-up needs.

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MLMIC SILO

A Customized Protection Program for Employed Physicians

Every aspect of the field of medicine is evolving, and medical professional liability coverage (MPL) is no exception.

Keeping in tune with and striving to address the changing needs of the market and customers we serve, MLMIC Insurance Company has introduced SILO, an insurance program designed to provide comprehensive protection for employed physicians.

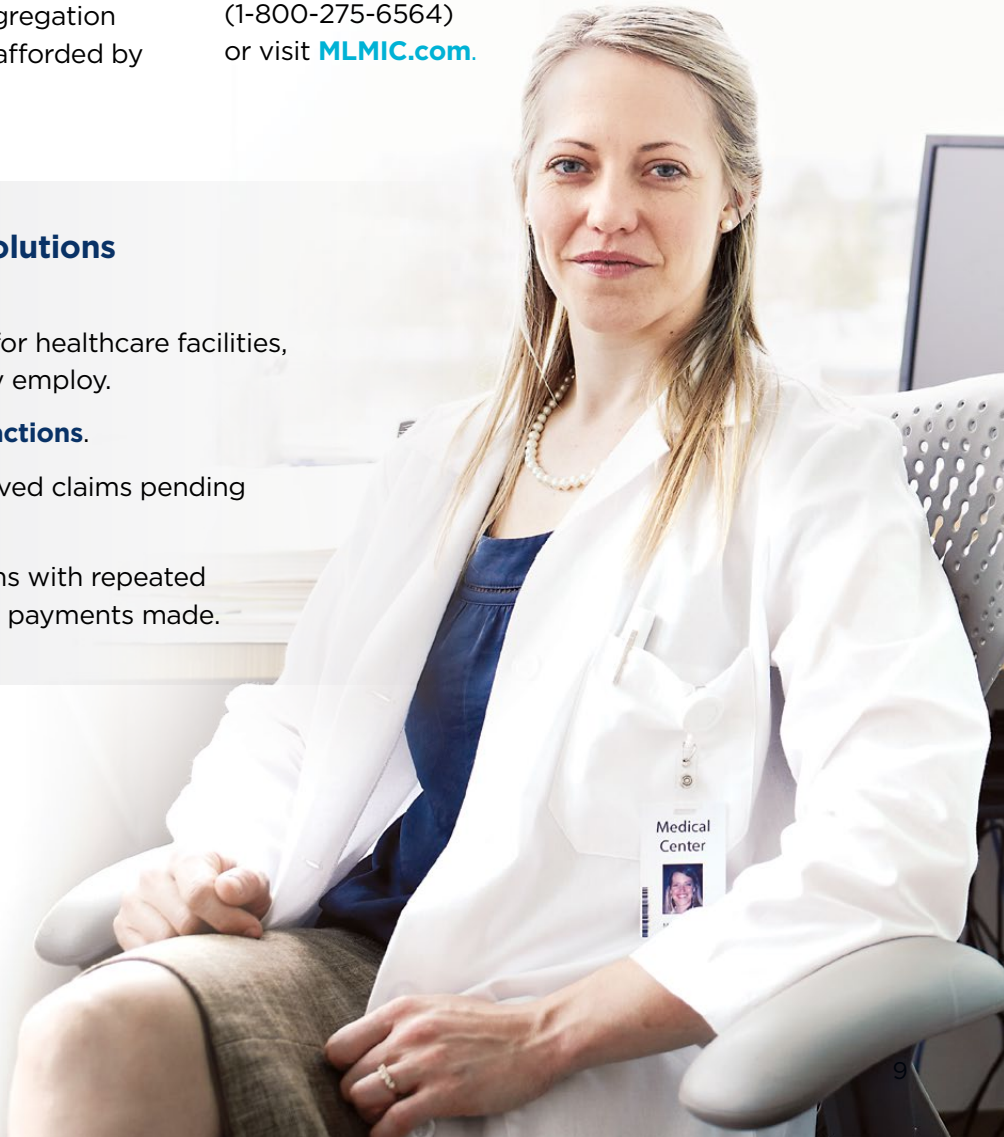
Some of the many benefits that SILO offers include pricing expertise, risk-sharing options, segregation of risk, settlement authority, and savings afforded by a united defense.

SILO also offers concierge services and risk mitigation strategies, such as dedicated teams for early intervention and regularly scheduled status updates; collaborative claims management and data analytics; customized risk management services and educational offerings; and 24/7 access to dedicated legal counsel.

To learn more about SILO and how MLMIC can help you with this exciting new program, please contact us at **(800) ASK-MLMIC** (1-800-275-6564) or visit **MLMIC.com**.

SILO was created to provide solutions for various risks, including:

- **Steadily increasing MPL loss costs** for healthcare facilities, practices, and the professionals they employ.
- **The frequency of multi-defendant actions**.
- **The financial uncertainty** of unresolved claims pending for years.
- **"Outlier" physicians** who have claims with repeated frequency and severity of indemnity payments made.



New "Paperless" Document Option Available on MLMIC's Secure Portal

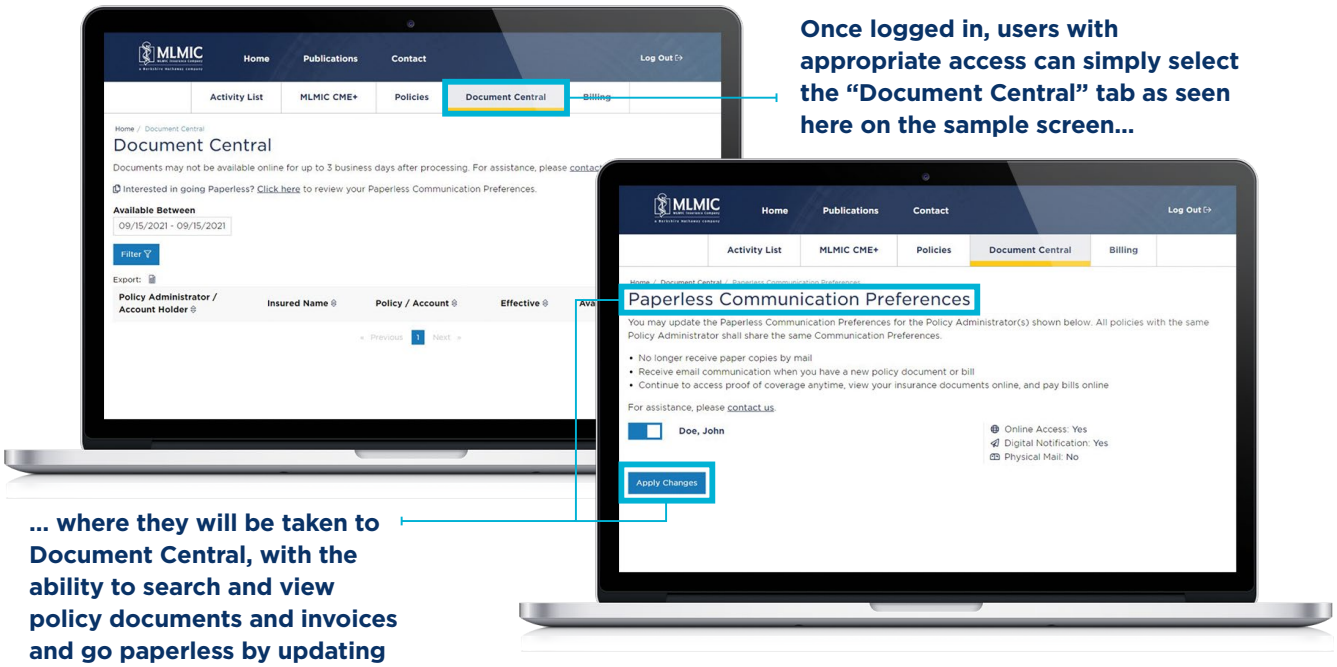
Save Time, Effort, and Paper by Accessing Your Policy Documents Online

Receive Timely Email Notification of New Policy Documents and Invoices Upon Availability by Opting in to "Digital Notification Preferences"

Policy Documents and Document Central

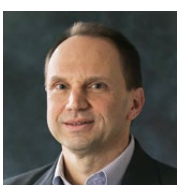
As previously communicated in earlier editions of this publication, active policyholders or their authorized representatives who establish applicable access on the MLMIC portal can view and download the account holder's policy documents and invoices. Insureds who are first-time visitors or others authorized to transact on an insured's behalf can establish portal access by creating login credentials on the Company's website at MLMIC.com. The process is simple, and can be completed quickly.

Further enhancing online document access is the newly implemented ability for authorized users to opt in to paperless documents and select the "Digital Notification" preference. By enabling this feature, the authorized user on the account will receive an email notification each time a new policy document or invoice is available for viewing. To sign up for this option, log in to the policyholder's account and select the "Document Central" tab as indicated below, which will provide access to the account's online policy documents and invoices. **If this tab does not appear in the user's portal view, please call (888) 234-0752 for assistance.**



Once logged in, users with appropriate access can simply select the "Document Central" tab as seen here on the sample screen...

... where they will be taken to Document Central, with the ability to search and view policy documents and invoices and go paperless by updating their Paperless Communication Preferences.



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At such point, users will have the ability to access the paperless delivery option by clicking on the "Click here" link as shown, which will open to the Terms of Use for this feature. Upon the user's acceptance of such, the Paperless Communication Preferences menu will appear and the desired document delivery options may then be selected.

It is important to note that users will no longer receive paper copies of their documents by mail if the paperless option is selected. However, users have the ability to change preferences at any point by logging in to their accounts should they wish to revert to paper copies of documents by mail.

Online Premium Payments

As an ongoing reminder, we would like to encourage users to avail themselves of the MLMIC portal to make electronic premium payments online. Authorized portal users can make expedited electronic premium payments by clicking on the Billing tab upon logging in to their online accounts, which will provide general billing details of the account holder, including the ability to view the account's most recent invoice. Payments can be made for stated amounts (total or minimum amounts due) or other selected amounts. Payment methods include Automated Clearing House (ACH) and credit card options. There is no additional fee for ACH payments; however, a 3% surcharge fee is incurred for all credit card payments. Successfully completed payments will generate an automated email receipt, delivered from our payment processing partner, which is sent to the email address on the account to confirm the transaction.

As electronic payments ensure timeliness of remittance, process more expeditiously than traditional methods, and are more secure, we strongly suggest that our readers consider this option as the preferred method when making premium payments.

View the Latest MLMIC Resources Online

TALK STUDIO

Medical Liability Depositions in New York

Watch our extended video series on the deposition process at **MLMIC.com/talkstudio**

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MLMIC INSIDER

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See results from our recent vaccine survey at **MLMIC.com/mandate**

Inadequate Patient Assessments?

Explore the causes of diagnostic errors and substandard treatment at **MLMIC.com/assessment**

Effective Telehealth Patient Engagement

Review effective strategies for patient engagement following the move to "virtual visits" at MLMIC.com/telehealth

‹ *Interoperability — Ensuring Technology Works for You, continued from page 3*

To stay vigilant and mitigate potential liability risks, please consider the following recommendations:

1. **Establish an enterprise-wide management plan** to support patient safety by creating policies, guidelines for use, and roles and responsibilities for technology and interoperability processes. It is important to maintain strong communication between the clinical engineering and IT departments, and to involve your Risk Manager in the development of these programs.

2. **Develop a multidisciplinary "Selection, Acquisition, and Replacement Plan" to address:**
   - Organizational needs
   - Regulatory requirements
   - Technology obsolescence
   - Opportunities to increase services and/or technology
   - Standardization of processes and devices, where possible
   - Additional budgetary considerations

3. **Maintain inventory and records documentation:**
   - Include all medical equipment and devices.
   - Develop a criticality rating system, which is used to determine how often equipment should be inspected or maintained.
   - Outline inspection and maintenance schedules.
   - Document any testing and calibration prior to initial use, as well as inspections, maintenance, and repair activities, including who performed the work, full device identification (model and serial number, internal tracking numbers, etc.), device location, and any manufacturer-specific requirements.

4. **Establish a change control plan** to specifically address compatibility and connectivity needs with new or updated devices and applications:
   - Assess whether customizations still function appropriately following updates.
   - Review interface maps.

5. **Consider contract language** requiring technology vendors to provide advance notice of impending changes.

6. **Perform periodic functionality testing**, which is especially important following any security updates.

7. **Provide the following guidance** for the management of unexpected events:
   - Provide immediate care for the patient, if required.
   - Remove suspect or malfunctioning equipment from use.
   - Sequester the piece of equipment using lockout-tagout, a safety procedure used to ensure that machines are properly shut off and not able to be started up again prior to the completion of maintenance or repair work.
   - Promptly notify your professional and general liability carrier if patient harm occurred as a result of equipment malfunctioning. Contact your liability carrier before returning the device to the vendor or sending it for outside inspection.
   - Include these events in your event reporting system.

8. **Monitor all device recalls and alerts.**

9. **Maintain a strong and ongoing training and competency program.**
   - Education should be provided by a knowledgeable expert.

10. **Communicate to staff the importance of reporting issues or suspected issues.**

11. **Address any non-standardization/differences in devices** that may look alike, but function differently:
    - Alarm parameters
    - Dose and rate settings on pumps
    - Connections and tubing, etc.

12. **Explain default settings** and how to appropriately change them if necessary.

13. **Establish quality/risk activities specific to each technology** and its interoperability requirements.
    - Track trends and analyze events that involve technology interoperability as a contributing factor.

14. **Develop a policy and procedure for instances when patients are allowed to use their own devices**, as the facility may be at risk of liability for issues such as appropriate use, proper maintenance, repair, or storage. According to **ECRI**, "The key question to consider is, 'Is there a risk of serious injury or death should the equipment fail?'"

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Request a quote at **MLMIC.com/psp**, or contact your broker today.

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