



the **REPORTER**

CME **VACCINES:** **A PRACTICAL** **GUIDE FOR** **PHYSICIANS**

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Q2

Quarter 2, 2021

CME - VACCINES: A PRACTICAL GUIDE FOR PHYSICIANS

by Karin Zaner, JD



OBJECTIVES

Upon completion of this course, the physician will be able to:

1. discuss the FDA's process for vaccine development and approval;
2. list the required steps to become a vaccine provider;
3. explain the legal immunities associated with giving vaccinations; and
4. describe the AMA's position on a physician's responsibility regarding vaccines.

COURSE AUTHOR

Karin Zaner, JD of Zaner Law, PC, represents Texas physicians and physicians in training. She earned her Bachelor of Arts with special honors in the Plan II Honors Program at The University of Texas at Austin, before earning her law degree from the UT School of Law. Ms. Zaner serves on both the College of Liberal Arts Advisory Council and the Plan II Advisory Council at The University of Texas at Austin and is a member of the College of the State Bar of Texas.

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This course has been designated by TMLT for 1 credit in medical ethics and/or professional responsibility.

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It should take approximately 1 hour to read this article and complete the questions and evaluation form.

RELEASE/REVIEW DATE

This activity is released on May 17, 2021 and will expire on May 17, 2024.

Please note that this CME activity does not meet LSA's discount criteria. Physicians completing this CME activity will not receive a premium discount.

INTRODUCTION

As COVID-19 vaccinations continue across the United States, questions of best practices, patient priority, vaccine storage, and professional liability have all come into focus. One thing the COVID-19 vaccination effort has revealed is a need for clarity among the general public about how vaccinations are developed and used. This article offers physicians a deeper context on vaccinations to help them with patient interactions about this important topic.

Vaccination is a highly effective method for preventing or containing certain infectious diseases for adults and children. Many infectious diseases experienced by earlier generations, like polio and measles, are significantly less common today because of vaccine use.¹

Immunization protects entire communities, as those who are not able to get vaccinated due to underlying health conditions or who choose not to be vaccinated rely on community (or "herd") immunity to protect them. Community immunity happens when enough people are immune to a disease, mostly through vaccination or prior illness, that the disease cannot effectively spread.

The percentage of people who need to be immune to achieve herd immunity varies with each disease. It is unknown what percentage of people need to be vaccinated for COVID-19 to achieve community immunity.²

Without adequate community participation in recommended vaccines, vulnerable populations such as senior adults, people with underlying conditions,

immunocompromised people, and children are left at greater risk of exposure to serious infectious diseases.³ Babies, children, adolescents, and adults are given vaccines to prevent infectious diseases, which means that safety and efficacy is of utmost importance.⁴

This article will provide an overview of the general structure of the vaccine approval and distribution system in the United States (including Emergency Use Authorization) as well as the protocols, guidelines, and best practices for providers in administering vaccinations.

This article will also discuss the federal statutes that provide important legal immunities (for providers, manufacturers, and other participatory third parties), as well as the legal framework for compensation to vaccine recipients who experience serious adverse effects.

Finally, this article will raise and explore some of the ethical issues facing vaccine providers.

THE U.S. VACCINE APPROVAL SYSTEM

The U.S. Food and Drug Administration (FDA) is the federal agency responsible for medical product regulation in the United States. The FDA states that “[e]nsuring the safety and effectiveness of vaccines is one of FDA’s top priorities.”⁴ In order for a vaccine candidate to become available to the general public, it must first undergo rigorous safety and efficacy reviews by the FDA.

Vaccine manufacturers first collect and submit data to the FDA. The FDA’s Center for Biologics Evaluation

and Research (CBER) ensures that the FDA’s rigorous scientific and regulatory processes are followed by vaccine developers and manufacturers.⁴

In addition, two separate committees independently review the safety and efficacy data. The first committee is the FDA’s Vaccines and Related Biological Products Advisory Committee (VRBPAC), which evaluates data concerning safety, effectiveness, and appropriate use of vaccines and provides advice to the Commissioner of the FDA.⁵ The second committee is the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC). The ACIP provides guidance to the Director of the CDC and recommendations on the use of vaccines based on disease epidemiology, vaccine safety, vaccine efficacy, quality of evidence reviewed, economic analyses, and implementation issues.⁶

STAGES OF VACCINE APPROVAL

Vaccine developers and manufacturers generally engage in the following stages for vaccine approval.

- **Research and discovery:** Scientists develop a rationale for a vaccine based on how the infectious organism causes disease and conduct laboratory research to test such concepts.
- **Pre-clinical phase:** Additional laboratory research and testing in animals is conducted to obtain information about how the vaccine works, including whether it would be effective and safe for humans.
- **Clinical development:** This stage includes the submission of the Investigational New Drug



application (IND), the FDA's assessment of the preclinical data, and then test Phases 1, 2, and 3 under the oversight of the FDA.

- **Manufacturing assessment:** Data is collected and submitted that supports the proposed manufacturing processes, facilities, and product characterization. Other submitted data includes a demonstration of lot-to-lot consistency, a review of "lot release protocol," a template of tests to be conducted on the vaccine post-approval, and inspections of facilities and operations by the FDA. All data submitted is to facilitate commercial-scale manufacturing.
- **Approval process:** Submission of Biologics License Application (BLA) to the FDA for approval to distribute and market the vaccine for use in the U.S., along with prescribing, indications, usage, dosing, and administration specifications.
- **FDA oversight:** Monitoring for safety and effectiveness and to identify uncommon adverse events or long-term complications, as well as other post-approval monitoring mechanisms such as "lot release."^{4,7}
- **Various other safety surveillance systems:** Review for approval may also be necessary from such systems as the Vaccine Adverse Event Reporting System (VAERS), the FDA BEST (Biologics Effectiveness and Safety) program and the FDA Sentinel Program, the FDA and Centers for Medicare & Medicaid Services (CMS) partnership, and the CDC's Vaccine Safety Datalink and Clinical Immunization Safety Assessment (CISA) Project 4.⁸⁻¹³

In addition, new systems have been developed for specific vaccines on an as-needed basis. For example, the v-safe smartphone-based tool uses text messaging to initiate internet-based survey monitoring and provides telephone follow up to anyone who reports medically significant adverse events related to COVID-19 vaccines.¹⁴

EMERGENCY USE AUTHORIZATIONS

In public health emergencies (PHE), such as the ongoing COVID-19 pandemic, the development process may be expedited given the urgent need for safe and effective vaccines. During a PHE, manufacturers may submit a request for Emergency Use Authorizations (EUA) to the FDA to facilitate the availability and use of their vaccine after meeting certain criteria.

An EUA generally contains the following data:

- chemistry, manufacturing, and controls information;
- nonclinical data and information;
- clinical data information; and
- administrative and regulatory information.

The FDA evaluates the need for pre-clinical studies and determines whether human trials can begin by considering

all relevant data about the vaccine and closely related vaccines. The design of the specific clinical study for the vaccine is evaluated and considered before human trials begin.

Adaptive trial designs are intended to expedite clinical trial decisions based on preliminary results from earlier trials, which can facilitate efficient clinical development. This may reduce the size and duration of the trial and demonstrate an effect if one exists. The FDA states on its website: "There is no predetermined timeline for vaccine development. Typically, the better the scientific understanding of a pathogen and the disease it causes, the more efficient vaccine development."⁴

BECOMING A VACCINE PROVIDER

There are various required steps to becoming a vaccine provider. While requirements differ depending on the state and particular vaccine, such steps generally include the following. (Texas requirements for becoming a COVID-19 vaccine provider are included here to illustrate these steps.)¹⁵

1. **State registries:** In order to administer vaccines, a provider must enroll in the state immunization registry for the particular vaccine. In Texas, the Department of State Health Services (Texas DSHS) runs the registry,¹⁶ and requires enrollment in ImmTrac2.¹⁷

As part of this process, a provider needs to complete the CDC's Vaccination Program Provider Agreement for the specific vaccine at issue.¹⁸ The provider should also list the health care providers at that location who will be responsible for vaccination.

After completing enrollment, a provider will receive an email confirming registration. Once approved, a provider will receive another email confirming status as a vaccine provider for the vaccine.¹⁹

2. **ACIP requirements:** Providers must administer the vaccine in accordance with all requirements and recommendations of the CDC and the CDC's Advisory Committee on Immunization Practices (ACIP) for each type of vaccine.²⁰
3. **Reporting to the CDC:** Certain reporting within a specific timeframe may be required by the CDC. For example, within 24 hours of administering a dose of COVID-19 vaccine, providers must document the vaccination in the recipient's record and report required information to the relevant state, local, or territorial public health authorities. Details of required information (Vaccine-Administration Data) for reporting can be found on the CDC's website at <https://www.cdc.gov/vaccines/covid-19/reporting/overview/index.html>.²¹

4. **Submission of data:** If the CDC requires it, providers must submit Vaccine-Administration Data through either (1) the immunization information system (IIS) of the state and local or territorial jurisdiction, or (2) another system designated by the CDC according to CDC documentation and data requirements.
 5. **Preserve record for at least three years:** Providers must preserve the record for at least three years following vaccination, or longer if required by state or local law. Such records must be made available to any federal, state, local, or territorial public health department to the extent authorized by law.
 6. **No cost to patient:** Depending on the vaccine, the CDC may prohibit providers from selling or seeking reimbursement for the vaccine and any adjuvant, syringes, needles, or other constituent products and ancillary supplies that the federal government provides without cost to the provider. This has been the case with the COVID-19 vaccines.¹⁵
 7. **Ability to pay:** Depending on the vaccine, the CDC may require providers to administer the vaccine regardless of the recipient's ability to pay vaccine administration fees. Again, this has been the case with COVID-19 vaccines.¹⁵
 8. **Provide EUA/VIS fact sheets:** Providers must provide an approved EUA fact sheet or vaccine information statement (VIS), as required, to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative.²² For the COVID-19 vaccine, providers must provide the applicable EUA for the specific vaccine given. Fact sheets for the following vaccines are found here:
 - a. **Johnson & Johnson:** <https://www.janssenlabels.com/emergency-use-authorization/janssen+COVID-19+Vaccine-Recipient-fact-sheet.pdf>²³
 - b. **Moderna:** <https://www.modernatx.com/covid19+vaccine-eua/eua-fact-sheet-recipients.pdf>²⁴
 - c. **Pfizer-BioNTech:** <https://www.fda.gov/media/144414/download>²⁵
 9. **Safe delivery:** To ensure safe delivery of the vaccine, providers must comply with any guidance for immunization services provided by the CDC for a particular vaccine.²⁶
 10. **Storage and handling:** Providers must comply with any CDC requirements for vaccine management and storage, which may include chain of custody and temperature, expiration dates, as well as the requirement for preservation of all vaccine records for a minimum of three years or longer if required by state or local law.²⁷
 11. **Unused, spoiled, expired, or wasted vaccines:** Providers may be required to report the number of doses of the vaccine that were unused, spoiled, expired, or wasted as required by the relevant jurisdiction. This has been the case with the COVID-19 vaccines.
 12. **Disposal:** Providers must comply with all federal instructions and timelines for disposing of vaccines, including unused doses.²⁸
 13. **VAERS reporting:** Providers must report moderate and severe adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS) at <https://vaers.hhs.gov/>.
 14. **Vaccination record card:** If required, providers must provide a completed vaccination record card to the vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative. This is a requirement for COVID-19 vaccinations. All COVID-19 vaccine shipment containers include COVID-19 vaccination record cards.
 15. **FDA and state vaccination laws:** Providers must comply with all applicable requirements as set forth by the FDA as well as all applicable state vaccination laws. For example, for the COVID-19 vaccines, providers must adhere to the requirements in the applicable EUA for the specific vaccine given.
- In addition, the CDC has resources on individual vaccines, which are specifically designed to guide providers in vaccine education and administration. For example, all COVID-19 vaccine shipments include a specific quick reference guide for health care professionals detailing basic storage, preparation, and administration information.²⁹
- The CDC also provides specific tool kits for medical centers, clinics, pharmacies, and clinicians to educate their staffs; for health care professionals and pharmacists to educate patients; for long-term care facilities to educate staff, residents, and their families; and for public health departments and their partners to educate communities. These resources include sample messages for use on social media channels, as well as educational videos and other CDC resources that can be used or posted online.³⁰⁻³³
- In particular, a CDC slide presentation from January 2021, "Building Confidence in COVID-19 Vaccines Among Your Patients" is a well-organized, fact-based, and concise example of the types of educational materials that the CDC makes available to providers during the ongoing pandemic. It is found at https://www.cdc.gov/vaccines/covid-19/downloads/VaccinateWConfidence-TipsForHCTeams_508.pdf.³⁴



DISCUSSING COVID-19 VACCINATION WITH YOUR PATIENTS

With the introduction of vaccines for COVID-19, many patients are eager to become vaccinated and return to a more recognizable, pre-pandemic version of life – visiting family and friends in person, returning to the office and the classroom, and venturing into stores and restaurants.

However, other patients are feeling hesitant due to vaccination myths and misinformation. Here is a brief list of common concerns to address when speaking with those who are vaccine hesitant.^{57, 58, 59}

Myth: The COVID-19 vaccines are not safe and have not been adequately tested.

According to the FDA, the COVID-19 vaccines are effective and safe. “The vaccines have undergone the most intensive safety monitoring in U.S. history, and vaccine developers followed all the necessary steps during clinical trials.” The Pfizer and Moderna vaccines were developed with messenger RNA (mRNA) technology which allowed for faster vaccine development and has been in use for years.

Myth: The vaccines were developed too quickly, and shortcuts were taken.

Neither science nor safety shortcuts were taken to develop the vaccines. They are a result of existing research, increased priority, unprecedented collaboration, and generous funding. The human clinical trials were also larger than usual for human trials, enrolling up to 45,000 participants, as opposed to a typical trial with less than 3,000 participants. All of these efforts contributed to the expedited development of safe and effective vaccines.

Myth: The vaccine will give me COVID-19.

None of the vaccines contain a live strain of the virus. Therefore, the vaccine will not give you COVID-19. The mRNA vaccine contains a “blueprint” of a small, non-living piece of the virus. Your body will use this blueprint to build antibodies to the actual virus should you ever become exposed to it.

You may experience side effects from the vaccine that will make you feel sick, but these symptoms are the result of your body working to strengthen your immune system. Should you become infected, your body will now know how to respond to the actual virus and fight it more effectively. Common side effects felt after receiving a COVID-19 vaccine are soreness at the injection site, fatigue, headache, body aches, or mild fever. But these side effects only last one to three days, if experienced at all.

Myth: The vaccine will alter my DNA.

Your DNA will not be altered. The vaccine’s mRNA does not and cannot interact with your DNA because DNA is stored within your cells’ nuclei, and while the vaccine mRNA does enter your cells, it cannot enter the nuclei of your cells.

Myth: The vaccine will make me sterile or infertile.

There is no evidence that the COVID-19 vaccines could result in sterility or infertility. However, COVID-19 illness may pose a serious risk to an ongoing pregnancy and the mother’s health. Pregnant patients should discuss getting the vaccine and any concerns they have with their physician.

Myth: The vaccines will not protect me against new variants of the coronavirus.

Data has found that the vaccines appear to be effective against several new strains of SARS-CoV-2. COVID-19 has less of a chance of spreading and being a health hazard when more people are vaccinated.

Myth: I’ve already had COVID-19, so I don’t need the vaccine.

It is possible to become re-infected with COVID-19. Getting vaccinated will help minimize symptoms in the event you become re-infected.

It is also important to remind your patients that even though they have been vaccinated, they still need to follow current COVID-19 safety precautions.

LEGAL IMMUNITY AND COMPENSATION UNDER FEDERAL LAW

Any discussion of vaccines should include the legal remedies and defenses that exist for patients, providers, and manufacturers should a serious adverse reaction occur. While such legal remedies and defenses are state specific, there are federal statutes that preempt state laws in certain situations. Consult with various state resources and websites as well as legal counsel in your state to understand such specific state laws.

For patients adversely affected by vaccines, these federal laws may provide a certain framework for compensation that allows these patients to recover damages, sometimes even without a specific factual finding of causation. For providers, manufacturers, and others involved in providing vaccines, these federal laws provide legal immunities from liability under certain specific factual circumstances.

PREP ACT IMMUNITY FOR VACCINES IN PHEs

A primary federal law that provides legal immunity to providers (as well as manufacturers and others) for vaccines needed during a PHE is The Public Readiness and Emergency PREParedness Act (PREP Act). The PREP Act protects those involved in the development, manufacturing, and administration of vaccines from liability, as well as others involved in the necessary testing, diagnostic services, and other support services.³⁵

The PREP Act was enacted by Congress in 2005 and signed into law by President George W. Bush in the wake of the avian influenza outbreak. The PREP Act preempts state vaccine safety laws when emergency declarations are made by the United States Department of Health and Human Services (HHS), as was done in January 2020 for COVID-19.³⁶

Successful vaccination campaigns on a mass scale that are required during a PHE (now including COVID-19) would not be possible without some sort of legal immunity given to participatory third parties. Other vaccines covered by specific PREP Act declarations include smallpox and anthrax.^{37, 38}

Once a specific PREP Act declaration is issued by the HHS secretary, legal immunity from liability is provided for “claims of loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a [PREP Act] declaration...has been issued with respect to such countermeasure.”³⁹

PREP Act immunity applies to diseases, threats, and conditions determined by the HHS secretary to constitute “a credible risk” of a future public health emergency. By virtue of its definitions, the PREP Act broadly protects entities and individuals involved in the development,

manufacture, testing, distribution, administration, and use of such countermeasures.³⁹

For example, the PREP Act immunity applies to any “covered person,” defined as individual persons and entities, including (at the HHS secretary’s discretion), manufacturers, distributors, program planners, and qualified persons who prescribe, administer, or dispense countermeasures (e.g., licensed health care professionals).³⁹

The scope of PREP Act immunity includes the following: “design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasures.” Covered countermeasures include vaccines, drugs, and medical devices to be used against chemical, biological, radiological, and nuclear agents or terrorism, epidemics, and pandemics.^{39, 40}

PREP Act immunity covers tort liability for death (except in cases of willful misconduct for which the plaintiff has the burden to show), as well as physical, mental, or emotional injury, illness, or disability, and also can provide legal immunity for allegations tied to fear of any of these conditions. The framework for litigating and recovering for “willful misconduct” is set forth in the PREP Act as well.³⁹

In addition to the PREP Act statute, additional guidance is provided through advisory opinions by HHS’s office of general counsel, although such guidance is advisory only and not a final agency action or order (meaning there is “no force or effect of law”).⁴¹

The PREP Act also created the Countermeasures Injury Compensation Program (CICP), which provides benefits to certain individuals who sustain a covered serious physical injury as the direct result of the administration or use of covered countermeasures under a PREP Act declaration. The CICP “substitutes a no-fault, speedy compensation system in place of expensive and uncertain litigation.”⁴¹

The regulations implementing the CICP specify which serious injuries that warrant hospitalization are covered.⁴² Injuries that are not covered include emotional injuries, fear of injury, business losses, and other types of claims for which immunity is provided.⁴¹ Information about the CICP and filing a claim are available at the toll-free number 1-855-266-2427 or the CICP website at <https://www.hrsa.gov/cicp>.⁴³

CHILDHOOD VACCINES UNDER THE NCVIA

The federal National Childhood Vaccine Injury Act of 1986 (NCVIA) provides certain legal immunity to providers, manufacturers, and others for the routine administration of CDC-recommended vaccines to children.⁴⁴ This act

facilitated the creation of the National Vaccine Injury Compensation Program (VICP), a no-fault alternative to the traditional legal tort compensation system in court.⁴⁵

The VICP was established after lawsuits against vaccine manufacturers and health care providers threatened to cause vaccine shortages and reduce vaccination rates. The VICP is designed to be an “accessible and efficient forum” to provide compensation to people injured by certain vaccines. The NCVIA was amended in 2016 to update and expand the vaccines covered by the VICP.⁴⁵ The PREP Act clearly provides that nothing in it “shall be construed to affect the [VICP].”³⁹

The NCVIA mandates that all health care providers must report certain adverse events following vaccination to VAERS.^{8, 12, 46} The NCVIA requires that all health care providers who administer certain vaccines (e.g., vaccines against diphtheria, tetanus, pertussis, polio, mumps, rubella, hepatitis B, Haemophiles influenzae type b, and varicella) must provide a Vaccine Information Statement (VIS) to the vaccine recipient, their parent, or legal guardian before each dose. Current versions of all VIS are available at <https://www.cdc.gov/vaccines/hcp/vis/index.html>.⁴⁷

A VIS must be given with every vaccination, including each dose in a multi-dose series. Each VIS contains a brief description of the disease, as well as the risks and benefits

of the vaccine. Each VIS is developed by the CDC and distributed to state and local health departments, as well as individual providers.

Those filing claims under the VICP are not required to prove negligence on the part of the health care provider or manufacturer to receive compensation.⁴⁸ Also, the VICP publishes a Vaccine Injury Table that contains a listing of covered vaccines and associated injuries that makes it easier for some patients to receive compensation. The table lists and explains injuries and/or conditions that are presumed to be caused by vaccines unless another cause is proven.⁴⁹

Funding to compensate vaccine-related injury or death petitions for covered vaccines administered on or after October 1, 1988 are paid for by the Vaccine Injury Compensation Trust Fund, which is funded by a \$0.75 excise tax on each vaccine dose (i.e., those vaccines recommended by the CDC for routine administration to children). The VICP is administered by the HHS. Information about the VICP and filing a claim are available at the toll-free number 1-800-338-2382 or by email at vaccinecompensation@hrsa.gov.⁴⁵

A vaccine manufacturer or administrator may be afforded certain protections from liability if the vaccine is covered under the VICP. Under the NCVIA, persons with petitions of



vaccine-related injuries or deaths resulting from covered vaccines must first exhaust their remedies under the VICP before they can pursue legal actions against vaccine manufacturers or administrators.

To exhaust the remedies available under the VICP and pursue a legal action outside the VICP, a VICP petitioner must either withdraw a petition or reject the judgment under the VICP. Although the Act provides liability protections, these protections are not absolute. For example, a petition requesting damages of \$1,000 or less will be allowed in state or federal court without first filing a petition in the VICP. Also, if the VICP has paid a petitioner for a vaccine-related injury, the VICP may be able to pursue its own action against a vaccine manufacturer or administrator using its subrogation rights.⁵⁰

AMA'S CODE OF ETHICS POLICY ON VACCINES

The American Medical Association (AMA) Code of Ethics Opinions provides important guidance relating to vaccinations generally, as well as for use during the current COVID-19 pandemic. AMA Code of Ethics Opinion 8.7 (“Routine Universal Immunization of Physicians”) specifically states that (emphasis in bold added):

“[P]hysicians have an ethical responsibility to encourage patients to accept immunization when the patient can do so safely, and to take appropriate measures in their own practice to prevent the spread of infectious disease in health care settings. Conscientious participation in routine infection control practices, such as hand washing and respiratory precautions is a basic expectation of the profession. . .

In the context of a highly transmissible disease that poses significant medical risk for vulnerable patients or colleagues, or threatens the availability of the health care workforce, particularly a disease that has potential to become epidemic or pandemic, and for which there is an available, safe, and effective vaccine, **physicians have a responsibility to accept immunization** absent a recognized medical contraindication or when a specific vaccine would pose a significant risk to the physician’s patients.

Physicians who are not or cannot be immunized have a responsibility to voluntarily take appropriate action to protect patients, fellow health care workers and others. They must adjust their practice activities in keeping with decisions of the medical staff, institutional policy, or public health policy, **including refraining from direct patient contact** when appropriate. . .

Physician practices and health care institutions have a responsibility to proactively develop policies and

procedures for responding to epidemic or pandemic disease with input from practicing physicians, institutional leadership, and appropriate specialists. Such policies and procedures should include robust infection control practices, provision and required use of appropriate protective equipment, and a process for making appropriate immunization readily available to staff. During outbreaks of vaccine-preventable disease for which there is a safe, effective vaccine, institutions’ responsibility **may extend to requiring immunization of staff**. Physician practices and health care institutions have a further responsibility to limit patient and staff exposure to individuals who are not immunized, **which may include requiring unimmunized individuals to refrain from direct patient contact.**⁵¹

Further, the AMA Code of Ethics Opinion 8.4 (“Ethical Use of Quarantine & Isolation”) specifically states that:

A physician’s “long-recognized public health responsibility. . .in the context of infectious disease [may also] include the use of quarantine and isolation to reduce the transmission of disease and protect the health of the public. In such situations, physicians **have a further responsibility to protect their own health to ensure that they remain able to provide care**. These responsibilities potentially conflict with patients’ rights of self-determination and with physicians’ duty to advocate for the best interests of individual patients and to provide care in emergencies.

With respect to the use of quarantine and isolation as public health interventions in situations of epidemic disease, **individual physicians should:**

- (a) Participate in implementing scientifically and ethically sound quarantine and isolation measures in keeping with the duty to provide care in epidemics.
- (b) Educate patients and the public about the nature of the public health threat, potential harm to others, and benefits of quarantine and isolation.
- (c) Encourage patients to adhere voluntarily to quarantine and isolation.
- (d) **Support mandatory quarantine and isolation** when a patient fails to adhere voluntarily.
- (e) Inform patients about and comply with mandatory public health reporting requirements.
- (f) Take appropriate protective and preventive measures to minimize transmission of infectious disease from physician to patient, **including accepting immunization for vaccine-preventable disease**, in keeping with ethics guidance.
- (g) Seek medical evaluation and treatment if they suspect themselves to be infected, including adhering to mandated public health measures.

The medical profession, in collaboration with public health colleagues and civil authorities, has an ethical responsibility to:

- (h) Ensure that quarantine measures are ethically and scientifically sound:
 - (i) use **the least restrictive means** available to control disease in the community while protecting individual rights;
 - (ii) without bias against any class or category of patients.
- (i) Advocate for the highest possible level of confidentiality when personal health information is transmitted in the context of public health reporting.
- (j) Advocate for access to public health services to ensure timely detection of risks and implementation of public health interventions, including quarantine and isolation.
- (k) Advocate for protective and preventive measures for physicians and others caring for patients with communicable disease.
- (l) Develop educational materials and programs about quarantine and isolation as public health interventions for patients and the public.”⁵²

The AMA Code of Ethics Opinion 8.3 (“Physician’s Responsibilities in Disaster Response & Preparation”) specifically states that:

“Because of their commitment to care for the sick and injured, **individual physicians have an obligation to provide urgent medical care during disasters. This obligation holds even in the face of greater than usual risks to physicians’ own safety, health, or life.**

However, the physician workforce is not an unlimited resource. Therefore, when providing care in a disaster with its inherent dangers, **physicians also have an obligation to evaluate the risks of providing care to individual patients versus the need to be available to provide care in the future.**

With respect to disaster, whether natural or manmade, individual physicians should:

- (a) **Take appropriate advance measures**, including acquiring and maintaining appropriate knowledge and skills **to ensure they are able to provide medical services when needed.**

Collectively, physicians should:

- (b) Provide medical expertise and work with others to develop public health policies that:
 - (i) are designed to improve the effectiveness and availability of medical services during a disaster;
 - (ii) are based on sound science;
 - (iii) are based on respect for patients.

- (c) Advocate for and participate in ethically sound research to inform policy decisions.”⁵³

The AMA Code of Ethics Opinion 8.8 (Required Reporting of Adverse Events) specifically states that:

“Spontaneous reports of adverse events, especially rare or delayed effects or effects in vulnerable populations **are irreplaceable** as a source of information about the safety of drugs and devices. . . [P]hysicians are best positioned to observe and communicate about adverse events. . . . A physician who **suspects that an adverse reaction to a drug or medical device has occurred has an ethical responsibility to:**

- (a) Communicate that information to the professional community through established reporting mechanisms.
- (b) **Promptly report serious adverse events requiring hospitalization, death, or medical or surgical intervention** to the appropriate regulatory agency.”⁵⁴

Generally, these regulatory frameworks and statutes for vaccines enable providers to comply with these various ethics opinions, although situations can arise that challenge such ethical principles or put them in conflict. However, by reviewing and internalizing these ethics opinions as well as any others that might address the specific situation, a provider is best prepared to make good, sound decisions if or when such issues arise in their practice.

CONCLUSION

Issues surrounding vaccinations are especially critical to review and understand during the current COVID-19 pandemic. But even when the pandemic subsides, these issues will remain, including a provider’s role in ensuring that their communities are vaccinated at appropriately safe levels. The National Foundation for Infectious Diseases (NFID) sets forth on its website its “10 Reasons to be Vaccinated,” and these reasons will continue to exist even after the COVID-19 pandemic.⁵⁵

The NFID website also shares “real stories” of “real people” whose lives and loved ones have been seriously affected by their choice to vaccinate or not. Continued efforts at all levels as well as vigilance by providers to educate, prepare, and administer vaccinations is required to control the spread of serious diseases that can be prevented or mitigated by vaccination. And perhaps in doing so, such cautionary tales will save the lives of other “real people” in the future.⁵⁶

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Karin Zaner can be reached at karin@zaner.law.

INTRODUCING CORVUS: YOUR NEW CYBER SECURITY COVERAGE THROUGH TMLT

TMLT expands its coverage with advanced tools and services for Lone Star Alliance policyholders

*by Laura Hale Brockway, ELS, Vice President, Marketing, and
Wayne Wenske, Senior Marketing Strategist*

Cyber threats — including data breaches and ransomware attacks — can quickly become catastrophic for your practice if not dealt with quickly and decidedly. Cyber liability coverage helps your practice survive these incidents by covering losses from cyber-related events. This coverage is included with every TMLT or Lone Star Alliance RRG (LSA) medical liability policy.

After an in-depth analysis in 2020, TMLT determined that it would be best for our policyholders if we changed cyber liability business partners and began using more advanced tools and services in the cyber liability area.

Introducing Corvus Insurance—an insurance technology firm founded in 2017 and based in Boston, MA that provides some of the strongest and most advanced cyber risk management tools available. With Corvus, we've gone from Cyber Liability 1.0 to Cyber Liability 3.0.

On July 1, 2021, TMLT's new partnership with Corvus goes into effect with expanded and updated cyber liability coverage for TMLT and LSA policyholders. This partnership represents a more proactive approach for managing and defending cyber claims. And we are eager to offer these tools and services to you. See more at <https://www.corvusinsurance.com/>.

What puts Corvus ahead in the cyber liability insurance space? While the basic cyber liability coverage offered by Corvus Insurance is equivalent to the coverage offered by our current cyber partner, Tokio Marine, there will be a number of new services available.

A signature Corvus benefit will be the ability to provide a customized, individual assessment of your practice's online presence. This assessment is accomplished using the **Corvus Scan**, a non-invasive scan of your practice's public-facing website to detect cyber vulnerabilities that may exist on your site.

One of the biggest risks associated with being online is that a great deal of information about your practice's IT infrastructure is visible to the world at all times. This information is typically available through your practice website. The Corvus Scan looks at this information—both the obvious aspects, such as your public-facing website, and the less obvious ones, such as vulnerabilities in software embedded in your web applications. The Corvus Scan sees the same information a malicious actor would.

Once the scan is complete, you will receive a Dynamic Loss Prevention (DLP) Report that details any risks and vulnerabilities found. Some of the details will be of a low priority, presented as purely informational. Others may identify issues in your cyber security. All the information represents clues about where a malicious actor might find a way into your systems.

This report will also provide recommendations on how to remedy any specific vulnerabilities. These recommendations are drawn from cyber security best practices and prioritized by severity and by the potential to improve your security. They are written in clear language so you can understand the vulnerabilities and take action.

For example, the scan may reveal that you are running outdated web software, or that web encryption is not set up right. There might be websites and web applications still public that you had forgotten about. The scan might also tell you about well-known vulnerabilities within your operating system that need to be patched.

Following the first scan, Corvus will continue to monitor your practice site for new threats. A new scan and a new DLP Report will be sent to you quarterly that you can discuss with your IT service provider.

Additional details of coverage include the following.

- These changes to your cyber liability coverage will be automatically applied to your account at renewal. You will receive details about these policy updates with your policy renewal materials.
- There is no increased premium cost for this coverage; but effective July 1, 2021, there will be a \$2,500 per event deductible for cyber claims.
- Limits on cyber coverage remain \$100,000/\$100,000 (\$100,000/\$500,000 for entities). Higher limits will be available for purchase.
- For dentists covered under LSA, the limits are \$50,000 per claim / \$50,000 per policy period.

For more information about our partnership with Corvus Insurance, please visit TMLT's Corvus Cyber Resource site at <https://www.tmlt.org/medical-liability-insurance/expanded-cyber-liability-coverage>.

Questions? Please contact TMLT's customer service team at 800-580-8658 ext. 5050 or customerservice@tmlt.org.

Laura Hale Brockway can be reached at laura-brockway@tmlt.org.

Wayne Wenske can be reached at wayne-wenske@tmlt.org.

FAILURE TO DIAGNOSE AND TREAT WERNICKE'S ENCEPHALOPATHY

by Wayne Wenske, Senior Marketing Strategist



PRESENTATION AND PHYSICIAN ACTION

On March 29, Bariatric Surgeon A performed a laparoscopic sleeve gastrectomy on a 55-year-old man. The patient had a history of Type 2 diabetes, diabetic nephropathy, diabetic gastroparesis, fatty liver, hyperlipidemia, obstructive sleep apnea, GERD, and morbid obesity (BMI of 46).

Three days after surgery, the patient returned to the hospital's emergency department (ED) with pain in his abdomen. He was diagnosed with sepsis and intra-abdominal abscess. An interventional radiology procedure was performed to place a percutaneous catheter to drain the abscess.

Over the next three months, the patient returned to Bariatric Surgeon A and his primary care physician, Family Physician A, several times to follow up on the infection. During these almost daily visits, the patient consistently reported nausea, food intolerance, and weakness. The following is a summary of treatment provided during these visits.

- On April 27, a GI swallow conducted by Bariatric Surgeon A revealed a contained leak at the upper edge of the staple line communicating with the drain. The patient was referred to a gastroenterologist to discuss placement of a stent.
- On April 30, the patient saw Gastroenterologist A to evaluate the possible leak status and discuss a stent placement. Gastroenterologist A scheduled the patient for an EGD, but the patient declined treatment.
- On May 17, the patient saw Family Physician A who diagnosed an intra-abdominal abscess with persistent leak of the gastric sleeve. The patient was given IV antibiotics through a PICC line and was instructed to follow up with Bariatric Surgeon A.
- On May 22, the patient returned to Family Physician A with reports of vomiting and sore throat. Family Physician A's assessment was dehydration, hypotension, gastroparesis with intra-abdominal abscess with drain, and failure to thrive. The patient was administered one liter of fluid.
- On May 25, the patient called Gastroenterologist A and advised that he wanted to proceed with the stent procedure.
- On June 2 and 5, the patient returned to Family Physician A with continued vomiting. "Failure to thrive" was again noted in the patient record. Family Physician A encouraged the patient to increase oral intake, and IV fluids were given. The patient also requested that his PICC line be removed. The line was removed during the June 5 visit.
- On June 6, the patient returned to Bariatric Surgeon A. A CT scan was conducted in advance of the planned stent placement. The CT scan revealed

that the perigastric abscess had resolved and the drain remained in place at the site. A diatrizoate meglumine and diatrizoate sodium solution swallow was ordered for the next day, because the patient was reluctant to have the drain removed. The stent placement, which was to have taken place on June 12, was cancelled.

- On June 13, Bariatric Surgeon A performed an upper gastrointestinal series due to continued nausea and food intolerance. The GI series revealed a persistent leak at the staple line. Bariatric Surgeon A and the patient agreed to move forward with the stent placement.
- On June 23, Gastroenterologist A performed an EGD and placed the stent. His postoperative diagnosis was:
"Proximal gastric pouch leak status post argon plasma coagulation disruption of edges to help it close and status post placement of covered stent. Sleeve gastrectomy anatomy with dilation of the narrowed area in the mid portion."
- On June 27, Bariatric Surgeon A removed the patient's external drain. He was also seen by Family Physician A who ordered a new PICC line placement for IV fluid administration and home health care.
- On June 29, the patient was seen by Family Physician A for gastroparesis, severe caloric protein malnutrition, failure to thrive, and cachexia. He was given IV fluids.

On July 9, the patient came to the ED at a large medical center with weakness, fatigue, and anorexia over the past several months and confusion over the past few days, per his family. He was admitted to the hospital for testing.

The patient was evaluated by the hospital's Neurologist A. The patient's neurological examination suggested nutritional deficiency induced ophthalmoparesis with amnesic syndrome, which was highly suggestive of thiamine deficiency. The ataxic syndrome also supported the diagnosis.

The patient was diagnosed with Wernicke's encephalopathy (WE) and thiamine deficiency. It was managed with IV thiamine, B12, and folic acid. The results of an MRI of the brain were normal. On July 13, the patient was discharged to a rehab facility.

The neurologist noted that the patient required speech therapy and retraining for short-term memory loss.

ALLEGATIONS

A lawsuit was filed against Family Physician A, Gastroenterologist A, and Bariatric Surgeon A for gross negligence and failure to diagnose and treat WE, resulting in neurological damage.

LEGAL IMPLICATIONS

Defense consultants were mostly supportive of the care provided to the patient. One expert stated that Family Physician A should not have been expected to diagnose the anastomotic leak, and that the patient's neurological complications occurred fairly rapidly. This consultant felt there was not a significant delay in diagnosing WE once the major symptoms occurred.

Gastroenterologist consultants for the defense were supportive of Gastroenterologist A, arguing that his role was to place the gastric esophageal stent. He was not involved in the day-to-day management of the patient's post-operative state. These consultants felt Bariatric Surgeon A was responsible for the postoperative care from the sleeve gastrectomy.

Plaintiff expert opinions were less supportive. One internal medicine physician felt Family Physician A should have been aware of the patient's potential for inadequate nutrition and B-vitamin deficiency in light of the patient's bariatric surgery and his continued nausea and vomiting. Further, the patient's inadequate oral diet should have prompted Family Physician A to consider that the patient was at risk for multiple deficiencies (hydration, calorie-protein, and vitamin).

Another consultant felt the patient's chronic malnutrition led to the patient's thiamine deficiency and development of WE. This consultant stated that had the patient been given thiamine in late June/early July, the patient would not have experienced severe neurological symptoms.

Other plaintiff's experts noted that both Bariatric Surgeon A and Gastroenterologist A failed to document or order vitamin supplementation when treating a patient unable to maintain adequate oral nutrition. This failure to recognize and timely treat the patient's nutritional deficiencies led to significant thiamine deficiency and WE.

DISPOSITION

This case was settled on behalf of Family Physician A, Gastroenterologist A, and Bariatric Surgeon A.

RISK MANAGEMENT CONSIDERATIONS

The treating physicians testified that they had little experience or training with WE or with recognizing the primary symptoms associated with it — mental status changes/confusion, ataxia, and ophthalmoplegia. However, nutritional deficiencies and WE are known complications following bariatric surgery. WE carries a risk of catastrophic consequences when undiagnosed, such as permanent brain damage and death; thus, a high degree of clinical suspicion is required when treating patients at risk for WE.

WE is associated with acute thiamine (vitamin B1) deficiency and requires emergent treatment to prevent death and neurologic morbidity. Causes of thiamine deficiency include poor nutrition, chronic alcohol abuse, gastrointestinal disorders, bariatric surgeries, AIDS, hemodialysis, malignancies, and other systemic diseases.

"Thiamine deficiency can also result from infections, shock, prolonged nutritional deficiencies, or the administration of intravenous glucose prior to thiamine in malnourished or alcohol-dependent individual."¹

This case was also characterized by inadequate communication between the treating physicians. Testimony reflected that assumptions were being made about care provided from one provider to the next.

Family Physician A testified that he was aware that the patient was experiencing postoperative complications, but he did not contact Bariatric Surgeon A because he assumed the surgeon was handling the patient's postoperative care. Family Physician A also testified that there was no note of vitamin tests or prescriptions in the patient's record; however, he did not follow up with either Bariatric Surgeon A or Gastroenterologist A about his concerns.

Failure to properly communicate can result in conflicting care, ignored recommendations, and delays in addressing medical conditions. It is beneficial for referring physicians to speak directly with consulting physicians to discuss the patient's history, condition, treatment and expected outcomes, and to document these discussions.

Adequate and clear documentation can prevent confusion and potentially avoid adverse outcomes. A contemporaneous medical record makes it easier to defend a physician's actions in the event of a claim. Documenting physician-patient and physician-physician conversations also helps to ensure the medical record is complete and accurate.

SOURCE

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Wayne Wenske can be reached at wayne-wenske@tmlt.org.

IMPROPER PERFORMANCE AND DE-ESCALATION

by Wayne Wenske, Senior Marketing Strategist

PRESENTATION

On October 5, a 10-year-old boy was brought to a pediatric group practice by his mother for a well-child visit. The boy had a wart on his right wrist, and his mother asked Pediatrician A to remove it.

PHYSICIAN ACTION

Pediatrician A treated the wart with liquid nitrogen cryotherapy. He placed a cone over the wart to prevent the spread of liquid nitrogen. During the procedure, the patient cried out in pain. A small amount of cryotherapy drippage occurred from the funnel to the medial wrist around to the dorsum of the wrist, causing swelling and inflammation. After the procedure, Pediatrician A documented that wound care instructions and precautions were reviewed with the patient's mother and that a nurse would check in with the patient the next day.

When the nurse called the patient's mother the next day, the mother reported that the patient was experiencing painful, significant blistering with weeping on the boy's hand. She stated that the blistering was approximately two inches long by a half inch wide.

The nurse relayed this information to a different pediatrician at the practice, Pediatrician B, who stated the patient should return to the office. The mother made an appointment for later that day. In the meantime, the mother was instructed to wash the patient's wound with water only and to apply mupirocin ointment with a gauze pad and self-adhering wrap.

Pediatrician B saw the patient that afternoon. Upon inspecting the patient's wound, he documented it as a superficial blistered burn with no cellulitis. He instructed the mother and patient to keep the wound clean and dry and to continue using mupirocin ointment and cover with dressings. A follow-up appointment was scheduled for August 13 – one week later. The patient did not return for his scheduled appointment.

On August 16, the patient's father called the office to say that his son's wound looked bad, and he was worried about permanent scarring. He demanded the office schedule and pay for a dermatology appointment for his son. The pediatrician's office recommended a plastic surgeon instead of a dermatologist.

On August 17, the patient, his mother, Pediatrician B and Plastic Surgeon A met at the pediatrician's office. The mother was very angry, used excessive foul language, and made threats of legal action. The physicians expressed sympathy and told her they would work with her to cover any expenses to treat the patient.

Plastic Surgeon A examined the patient and diagnosed him with a second-degree burn. She debrided the burn eschar and noted no underlying signs of infection. On August 26, Plastic Surgeon A noted delayed healing and recommended excision and closure of the wound. She performed these procedures on September 1. The incision site was noted to be healing well. On September 15, extensive improvement was noted with an excellent long-term prognosis.

ALLEGATIONS

A lawsuit was filed against Pediatrician A and the pediatric practice alleging that an inappropriate technique was used to remove the patient's wart, causing significant burns to the wrist.

LEGAL IMPLICATIONS

A dermatology consultant for TMLT stated that cryotherapy is a well-established method for treating warts; however, burns and damage to surrounding skin are also possible when using this method. This consultant also stated that liquid nitrogen canisters come with spray tips with apertures of various sizes to use for different size lesions. When treating children, the smallest aperture is generally used.

This consultant stated that the photos of the patient's burn suggested that either 1) Pediatrician A may have used too large of an aperture; 2) there was a possible leak in the applicator tip; or 3) too much liquid nitrogen may have been applied too close to the skin. This consultant also stated that providers usually test spray the liquid nitrogen a few times into a cotton ball or tissue before spraying directly onto a patient to ensure the canister tip is appropriate and there are no leaks.

Other consultants expressed mixed opinions. While they all agreed that using liquid nitrogen was reasonable, they were critical of Pediatrician A's performance of the procedure. One consultant stated that the pediatrician should have attempted a more conservative approach to treat the child, as a sudden movement by a 10-year-old patient could lead to spills of liquid nitrogen.

Another consultant felt the lack of follow up by the parents may have contributed to the delayed healing of the patient's wound. This consultant noted the unpleasant, aggressive nature of the parents' behavior, which likely was not helpful.

DISPOSITION

This case was settled on behalf of Pediatrician A and the practice.

RISK MANAGEMENT CONSIDERATIONS

While the patient experienced a known complication of cryotherapy, this case was intensified by the emotional and aggressive nature of his parents. Treatment can be a confusing, frightening, and overwhelming experience for patients and their loved ones. Emotions can run even higher when treating children.

Handling the emotional outbursts and aggression of others can be "all in a day's work" for many health care professionals. But there are practical methods to help minimize and de-escalate difficult patients, caregivers, or guardians. Keep in mind: how a physician or staff member

responds to an emotional patient can determine whether the patient's behavior dissipates or escalates.

If you are aware of an upcoming difficult patient encounter, take extra time to prepare. Remind yourself to remain objective and focused on the care goals as opposed to any emotions you may feel. Doing so will help you better manage the encounter. Also, inform and prepare your staff in advance of the difficult situation.

If the patient becomes angry or disruptive during the encounter, remain calm and professional. This will help you maintain control of the situation. Also remain aware of how you may be perceived by the patient. Allowing an emotional reaction – returned anger, tears, fear, etc. – can escalate the situation.

“Body language or facial expressions can betray your feelings. Monitor your physical and emotional reactions. Learn to recognize any potentially negative physical signs, such as grimacing, crossing arms, or looking at the floor or ceiling instead of the patient.”¹

There are also a number of non-verbal de-escalation techniques to help diffuse an angry patient.

- Allow for personal space. Keep at least two arm's lengths between you and the patient to provide you both with adequate physical space to feel safe. Attempt to keep the room's exit clear and unblocked.
- Adopt non-threatening body language. Keep hands visible and not clenched. Avoid facing the patient directly; doing so could suggest confrontation.
- Maintain eye contact with the patient, but ensure it is appropriate to the patient and does not become a hardened stare.
- Position yourself at the patient's eye level, so you are either both standing or both sitting. Otherwise, the sitting person could soon feel intimidated, as if he or she is in a position of “weakness.”

Once you have attempted to de-escalate with non-verbal cues, calmly try to determine why the patient is angry. If the reason for the patient's anger can be identified, you will be better positioned to remain calm and provide appropriate support.

- Speak in a firm tone of voice.
- Use active listening techniques, such as open-ended questions, to let the patient know you are paying attention to his or her concerns. An example may be, “What is your primary concern?” or “How can I help you?”
- Paraphrase the patient's concerns back to him or her. Doing so demonstrates that you have listened and understand his or her viewpoint.

- “When possible, provide the patient with options to enable him or her to take an active part in solving the problem. Ask them how they would like to proceed. This will help the patient feel like they have some control in their care, positions you as an ally, and provides the patient with a greater understanding of their condition and care options.
- Preface any negative response with first letting the patient know you want to help. For example, ‘I wish I could do that for you, but . . .’ Or, ‘I'm here to help you and to find a solution, but right now this is the situation . . .’
- Acknowledge the patient's point of view by telling them, ‘I understand why you feel this way,’ or ‘I see how upset you are, and I understand.’
- Be factual and consistent. Repetition may be required if the agitated patient is having difficulty focusing on what you are saying. This includes making any requests (‘Please sit down, so we can discuss this’); setting boundaries (‘I want to help you, but you can't shout in here’); or offering solutions (‘I can help you today by writing a prescription for a week, then we can meet again’).
- Avoid using medical jargon. Speak as plainly and clearly as you can. Speaking beyond a patient's comprehension level may be interpreted as aggression.
- Don't engage in an argument or debate. Stick to your response; further explanations may lead to more disagreement.”¹

Focus on solutions as opposed to conflicts or errors. If the patient attempts to challenge you through aggressive questions or statements, keep bringing him or her back to discussing productive solutions and help. It is also helpful to allow the patient time to reflect on what is being discussed by allowing silences in the conversation. Silences can provide time for the patient to reflect and calm down.

Anxiety increases if a patient feels rushed into making decisions. If possible, give the patient time to consider treatment options and make decisions. Simply being present in the room with the patient without actions or words is a powerful way to support the patient and help him or her find peace with you and the situation.

However, if the patient becomes a continued source of conflict, aggression, or even violence, consider terminating the physician-patient relationship. There are several steps to follow when ending a patient relationship to ensure you are not liable for abandoning the patient. It is important to maintain the patient's continuity of care and your legal responsibilities.

The following resources for terminating the physician-patient relationship are found on the TMLT Resource Hub:

- “CME: Terminating the patient-physician relationship,” *the Reporter*, Quarter 4, 2017, <https://hub.tmlt.org/reporter/the-reporter-quarter-4-2017>
- “Terminating patient relationships: How to dismiss without abandoning,” <https://hub.tmlt.org/tmlt-blog/terminating-patient-relationships-how-to-dismiss-without-abandoning>
- “What every physician needs to know: Terminating the physician-patient relationship, Part 1,” <https://hub.tmlt.org/slideshare-all-slideshows/terminating-the-physician-patient-relationship-part-1>
- “What every physician needs to know: Terminating the physician-patient relationship, Part II,” <https://hub.tmlt.org/slideshare-all-slideshows/terminating-the-physician-patient-relationship-part-2>

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Wayne Wenske can be reached at wayne-wenske@tmlt.org.

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the **REPORTER**

LONE STAR ALLIANCE RRG

P.O. Box 160140
Austin, TX 78716-0140
844-595-8866
www.lonestara.com

EDITORIAL COMMITTEE

Robert Donohoe | President and Chief Executive Officer
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CONTRIBUTOR

Karin Zaner

DESIGN

Olga Maystruk



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