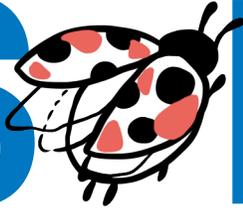


THE ADVISOR



MONTHLY COMPLIANCE COMMUNICATOR

GDPR AND YOU

WILL THE GDPR AFFECT YOUR PRACTICE?

What is the GDPR? General Data Protection Regulations (GDPR) is a set of laws passed by the European Union in May 2018, to provide rules for protecting electronic data on individuals in the European Union (EU). These regulations include similar security restrictions for Europe as HIPAA does for the USA. One of the biggest differences is that the information being protected is all private data not just health information. The GDPR also targets the information from companies that track consumer's internet history for the purpose of marketing products and services.

Why should laws passed in Europe matter to US companies? The GDPR is enforceable to any company that falls within the rules whether they are European or not. Additionally, other countries in Europe, Asia and Africa are starting to adopt the GDPR. This raises two questions:

1. What would make you subject to the GDPR?
2. Will the US adopt the same or similar laws as the GDPR?

1. What would make you subject to the GDPR?

Contrary to what the salespeople are telling you, it is unlikely that you will be covered under the GDPR. The official website of the European Union (EU) states that the GDPR does not apply to your business if: "Your company is a service provider based outside the EU. It provides services to customers outside the EU. Its clients can use its services when they travel to other countries, including within the EU. Provided your company doesn't specifically target its services at individuals in the EU, it is not subject to the rules of the GDPR."

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GDPR AND YOU

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The National Law Review here in the US says that the GDPR will apply to US healthcare only in the following circumstances:

- A part of your business is physically located within the EU.
- Your business offers goods or services (even if for free) to individuals in the EU. The offering of goods or services is more than mere access to a website or an email address. It includes, for example, marketing activities intended to recruit individuals in the EU to be patients at a hospital in the United States.
- You electronically monitor the behavior of individuals in the EU. This includes monitoring patients after they return to the EU, for example, as part of post-discharge patient engagement to prevent hospital readmission.

Are US healthcare practices subject to GDPR if a European citizen seeks treatment there while traveling or studying in the US?

No, protected health information is not Personal Data under the GDPR merely because it concerns an EU citizen. Instead, the data must concern an individual located in a country covered by the GDPR. The data collected from an EU citizen at a location in the United States will be subject to US law unless the data was solicited from an individual while the individual was physically located in the EU or the organization continues to monitor the EU citizen after the citizen returns to the EU, such as part of post-discharge patient engagement programs.

Would a US practice be subject to GDPR if it transmits patient records to a healthcare provider in Europe for a patient seeking treatment here?

Again, no. Practices here must follow US law, but the EU health care provider must protect the individual's privacy in accordance with GDPR while the individual is in the EU.

Are US practices subject to GDPR if it does not intentionally market to the EU but an EU resident visits its website?

No. Here is a good example from the GDPR website in the EU. A man in Paris went on the website for a pizza delivery service in Miami in order to purchase a pizza for a friend who lives in Miami. The Miami restaurant obviously doesn't deliberately market their services and products in Europe. This would be considered incidental and not deliberate. Thus, the pizza place does not fall under the jurisdiction of the GDPR.

To read the full National Law Review article: <https://www.natlawreview.com/article/does-gdpr-regulate-clinical-care-delivery-us-health-care-providers>

2. Will the US adopt the same or similar laws as the GDPR?

This is a topic of much debate here in the US. The general belief among the more credible sources is that America has already passed and will continue to pass laws to protect individual's private information. It is unlikely that those laws passed will be the same as the GDPR. The political and business culture in the US is very different from most of the world.

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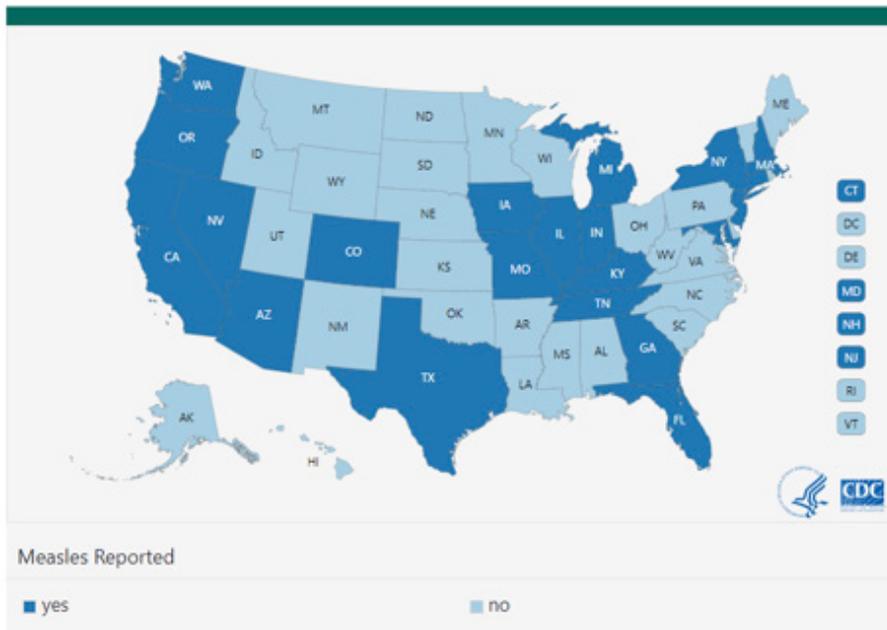
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MEASLES UPDATE

In case you haven't heard, we have a record number of measles cases documented in the US. At this point over 700 cases in 22 states have been reported, which is the highest number of cases since 2000, the year the disease was reported eliminated.

Healthcare workers are considered at risk for exposure. Have you documented the immune status/vaccines for at-risk workers in your practice? The following are acceptable documentation criteria from the CDC.

- Written documentation of adequate vaccination: two doses of measles-containing vaccine for school-age children and adults at high risk, including college students, healthcare personnel, and international travelers
- Laboratory evidence of immunity
- Laboratory confirmation of measles
- Birth before 1957 - If you were born after 1957 you need at least one dose of measles vaccine unless a laboratory confirmed that you had past measles infection or are immune to measles.



CDC Data

Reference and resources

<https://www.cdc.gov/measles/index.html>

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INSTRUMENT PROCESSING – THE SERIES

The Sterilization Process

To date we have focused on the cleaning process and the importance of ensuring instruments are adequately cleaned and appropriately wrapped or packaged. April's article ended with loading the sterilizer appropriately. This month we will discuss the actual sterilization process.

Sterilization can be defined as the process of making an object free from all living microorganisms. Whenever possible, sterilization of critical and semi-critical instruments should occur before reuse on a patient to reduce the likelihood of disease transmission or infection. There are several options available for sterilization, but the one used most frequently, with dependable results, is steam sterilization.

Advantages

- Non-toxic and inexpensive.
- Cycles are easy to control and monitor.
- Rapidly microbicidal and short cycle times.
- Least affected by organic/inorganic soils.
- Penetrates medical packing, device lumens.

Disadvantages

- Damages heat labile instruments.
- Not appropriate for heat-sensitive instruments.
- Moisture-sensitive instruments may dull or rust.
- Potential for burns.

Using the Steam Sterilizer

In previous articles the words manufacturer's instruction for use (IFU) have been penned. Before using any type of device for sterilization ensure that all the manufacturer's instructions for use (IFU) have been read thoroughly and appropriate policies and procedures are in place. Devices have clear instructions on maintenance requirements, preprogrammed cycles as well as instructions on proper loading of contents.

When determining how instruments should be reprocessed it is critical to review the IFU to ensure the correct cycle on the unit is used. In many cases the selection of a pre-programmed cycle is determined by the type of packaging material, but according to AAMI ST79 there is the possibility that programmed cycles and the cycle parameters recommended in the IFU could differ. If that is the case, then the manufacturer should be contacted to reconcile the difference between the two in order to ensure the instrument is appropriately sterilized prior to use.

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INSTRUMENT PROCESSING – THE SERIES

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Immediate Use Sterilization (Previously FLASH Sterilization)

Instruments should be appropriately wrapped and run through a complete sterilization process. Immediate use sterilization should only be used in emergency situations and not as a convenience measure. If this process is being used frequently, evaluate the number of instruments available. There may not be enough on hand to meet patient care demands.

Unloading the Sterilizer

Prior to removing instruments, check the unit for any error messages which may indicate that the indicated parameters for sterilization have not occurred. Depending on the type of unit in use, the manufacturer may recommend opening the door slightly at the end of the cycle. Instrument packages should not be removed from the sterilizer until they are completely dry and cool. Instruments also should not be removed when warm and placed on a cold surface to speed cooling. Once completed cool, the packages may be removed. During the removal process, packages should be inspected for any damage to the integrity of the packaging material, presence of moisture and for visual change of the external indicators. Once evaluated and no issues noted, the packages are ready for appropriate storage and use for patient care.

There are two more articles left in our series. Next month we will review appropriate monitoring and documentation of the sterilization process. Always remember: if it isn't documented, it isn't done.

Reference:

ANSI/AAMI ST79 2017. (2017). Arlington Virginia: AAMI, pp.63 - 65

NC SPICE PowerPoint presentation (2019).

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PROTECT YOURSELF

The Federal Trade Commission (FTC) requires businesses that deal with certain sensitive personal information to build programs or create procedures to detect red flags — activities that could be indicative of identity theft. Employees trained to look for these sorts of unusual and suspicious events can help protect both their companies and their customers from the pain and costs of identity theft. Though some red flags are specific to particular industries, here are some common situations that can show up in any company and may indicate identity theft.

- Documents that appear either altered or forged.
- Photos in identification documents that don't appear to match the presenter's age or gender.
- Complaints from customers about bills for products or services they never requested or received.
- Personal information that belongs to another person in your company's records.
- Personal information that doesn't match existing records, such as an address for a new credit application that doesn't match what is on file.
- Requests for new access or a new credit line immediately after a change to the user's address.
- Mail sent to a client or patient is returned as undeliverable on more than one occasion.

If any of these suspicious situations are discovered on new or existing accounts, bring them to the attention of your supervisor.

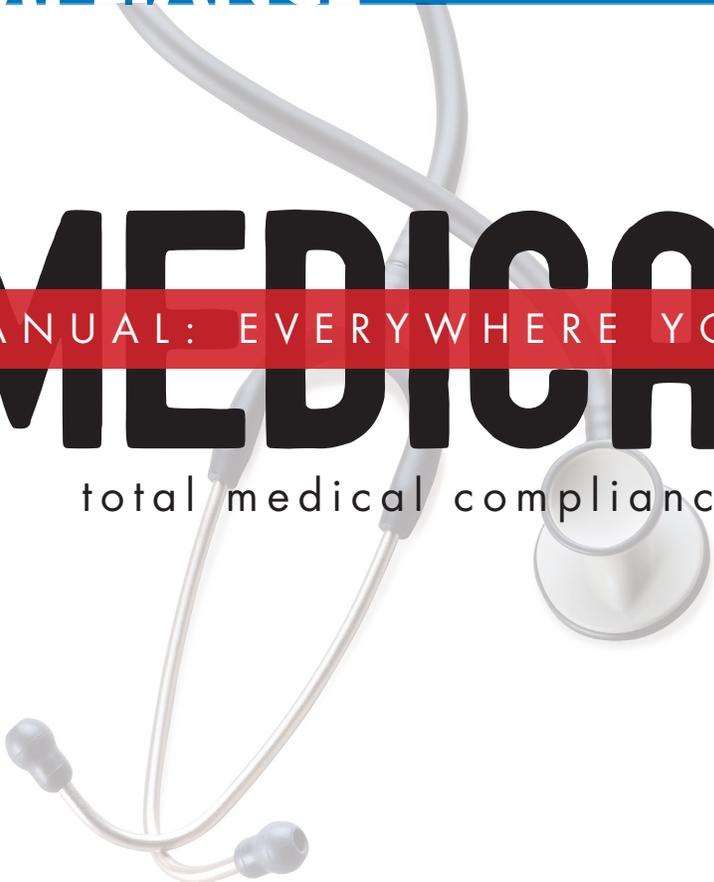
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EMANUALS: PAPER-FREE KEYBOARD CONVENIENCE

TMC has been offering an electronic version of our HIPAA and OSHA compliance manuals since late 2017 to serve the needs of healthcare practices that have already or are in the process of transitioning to a paperless environment. Rest assured that we will continue to sell and support paper manuals. The choice is yours; but if you have not yet checked out the electronic version of the TMC compliance manual, this spring may be the time for you to consider it.

The user-friendly electronic version of our compliance manual is easy to navigate and is searchable so you can quickly get the information you need without flipping through paper or scrolling through many pdf pages. The compliance forms you depend on are PDFs with fillable text fields. Instead of writing by hand on paper forms, you can save time and improve accuracy and legibility by filling the forms in with the keyboard and saving them to your eManual. Another great benefit of the eManual is the instant update feature. Anytime we make a change to the manual, those updates are immediately available to you.

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WORD SEARCH PUZZLE

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GETTING TO KNOW TMC EMPLOYEES



This month we would like to introduce our RN Director of Compliance and Education: Karen Gregory. Karen has over 20 years of experience working in an outpatient environment, both at the front line delivering patient care and in the management arena. She is passionate about both employee and patient safety and takes every possible opportunity to improve the quality of healthcare for all involved. Karen is currently the Director of Compliance and Education for TMC where she develops compliance materials in addition to training consultants and clients. She is a frequent speaker for professional organizations and at conferences nationwide on OSHA, HIPAA and Infection Control.

Karen has been selected as a Hu-Friedy Key Opinion Leader, is on the Editorial Review Board for the OSAP publication Infection Control in Practice, and serves on the Board of Directors for OSAP.

1. What is your must-have or go-to morning beverage? [Dunkin Donuts of course!](#)
2. What is the most fun or unusual item you keep on your desk? [An angel Finley painted for me](#)
3. What is the strangest or most fun job you've ever had? [Being a mom](#)
4. How far away from home is the farthest away you've ever been? [Hawaii](#)
5. What is your go-to item that you most often bring to potlucks? [Apple pie](#)
6. Where is your favorite place to listen to music? [On my walks](#)
7. What is the last movie you saw in a movie theatre? [Hotel Transylvania 3 - You can tell I am a Mimmie](#)
8. Do you have any phobias? [snakes and hotel fires](#)
9. What is the most daring thing you've ever done? [I am not a risktaker, thus my job is a compliance person.](#)
10. Do you collect anything? [Memories](#)
11. Do you or would you sing at Karaoke night? [Are you kidding me?](#)
12. Are you related even distantly to anyone famous? [Nope](#)
13. What is your favorite holiday? [Thanksgiving](#)
14. What was the last non-work-related thing you read? [Hope Heals](#)
15. Is your glass half-empty or half-full? [If it is coffee half-empty because I always want more](#)

IT'S YOUR CALL

OSHA Situation:

Warmer weather is here, and administrative employees often inquire about the rules for wearing open-toed shoes. What is OSHA's view?

HIPAA Situation:

My co-worker is loud when he talks to patients. Does the HIPAA Privacy Rule say anything about talking to patients if one might be overheard?

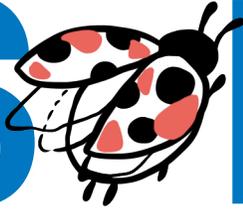
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INSTRUCTIONS

Print and post newsletter in office for staff review. Each member should sign this form when completed. Keep on file as proof of training on these topics.

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