

# THE ADVISOR

## MONTHLY COMPLIANCE COMMUNICATOR



### Steering Clear of Information Blocking

April 5, 2021 is the compliance date for the Information Blocking Rule issued last year by the HHS Office of the National Coordinator for Health Information Technology (ONC). Information Blocking is something that a healthcare provider, health IT developer, or health information exchange (HIE) does (or fails to do) that is likely to make it difficult or impossible for a patient's electronic health information (EHI) to be accessed, exchanged, or used. Unless a valid exception applies, Information Blocking is a violation of a patient's Right of Access under HIPAA and the Rule.

While the Rule does not directly change HIPAA, they do share some concepts and terminology. In fact, your practice or business may need to comply with this Rule even if you are not considered a covered entity or business associate under HIPAA (e.g., fitness apps), or your office does not use health IT software that is certified by the ONC's Health IT Certification Program (e.g., EHRs).

As with HIPAA, the Rule has eight exceptions that describe when an access request may be denied or provided in a different format than requested by the patient. In general, the eight exceptions are divided into two categories:

**Denying or modifying the format of an access request may be permitted if the healthcare provider reasonably believes that it:**

- 1** Prevents harm to a patient or another person.

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# HIPAA COMPLIANCE

- 2 Protects an individual's privacy.
- 3 Protects the security of the individual's EHI.
- 4 Qualifies as being infeasible under the Rule:
  - For reasons out of your control like a natural disaster.
  - Cannot be provided due to financial or technical restrictions, or by law.

In these situations, the patient must be notified within 10 business days of receiving the request with a reason why responding to the request is infeasible.

- 5 Is to maintain or improve health IT performance (e.g., unavailability of EHI due to system maintenance, response to a security threat, etc.)

## Procedures related to fulfilling requests/availability of EHI:

- 6 Content and manner – if the information cannot be provided in the technical format requested, it can be provided in an alternative manner described in the Rule or agreed upon by the patient.
- 7 Fees – this exception does not apply to fees charged to the patient, other person, or entity the patient requests to access their EHI. This exception refers to fees charged by software vendors to access, convert, or export EHI when using or switching health IT systems, and to avoid unfair competition that interferes with the access, exchange, or use of EHI.
- 8 Licensing health IT – contracts to access, exchange, or use EHI across health IT systems cannot be unreasonably delayed or contain terms that restrict a healthcare provider from switching health IT systems in the future, are discriminatory, or charge fees prohibited by the Rule.

Document all access requests, train your workers, and make sure policies and procedures are consistently followed. Doing so will help reduce the likelihood of non-compliance. More details about the exceptions will be provided in upcoming newsletters and TMC Client Portal materials.

TMC is committed to providing its clients superior compliance resources and support. Our compliance manuals and Client Portal offer policies, checklists, and guides to help make your compliance program a success.



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# COVID 19 VACCINE: JUST THE FACTS

## COVID 19 VACCINE: JUST THE FACTS

The vaccine to protect against COVID – 19 is now available in most areas. Because frontline healthcare workers are at higher risk of exposure to the virus you may have already received at least the first dose in the series. Still, many are weighing the risk/benefits of this new vaccine. The purpose of this article is to list the facts that are known at present about the vaccine.

**1** The vaccine followed the usual steps for testing and review. The American Dental Society, “COVID-19 Vaccination Key Facts”, provides important data from the clinical trials on the two vaccines currently available in the US.

### Information about the clinical trials

	Pfizer-BioNTech	Moderna
Link to FDA appraisal of the submitted data	<a href="#">Pfizer BioNTech data</a>	<a href="#">Moderna data</a>
Vaccine	BNT162b2	mRNA-1273
ClinicalTrial.gov registration	<a href="#">NCT04368728</a>	<a href="#">NCT04470427</a>
Number of people enrolled in the phase 3 clinical trial	36,621 participants randomized 1:1 to vaccine or placebo	27,817 participants randomized 1:1 to vaccine or placebo
Age of people in the trial	≥ 16 - 85 years of age	≥ 18 - 87 years of age
Second vaccine dose	21 days after 1 <sup>st</sup> dose	28 days after 1 <sup>st</sup> dose

**2** Side effects did occur in a large percentage of the participants in the vaccine trials. The most common reported side effect is injection site reactions, followed by flu-like symptoms. These reactions are normal signs that your body is building antibodies to protect you from the illness. The ADA’s “COVID-19 Vaccination Key Facts” document provides additional breakdown on the types of reactions reported.



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# COVID 19 VACCINE: JUST THE FACTS

## Safety

	Pfizer-BioNTech	Moderna
Injection site reactions	84%	92%
Flu like symptoms		
Fatigue	63%	69%
Headache	55%	63%
Muscle pain	38%	60%
Joint pain	24%	45%
Chills	32%	43%
Fever	14%	15%
Non-fatal serious adverse events	<0.5% in vaccine group <0.5% in placebo group	<1% in vaccine group <1% in placebo group
Deaths in the reporting period	N=2 in vaccine group N=4 in placebo group	N=6 in vaccine group N=7 in placebo group

- 3** The COVID-19 vaccine cannot make you sick with COVID-19. The vaccines that are in current use do not contain a live virus. While there have been reports of people becoming ill with COVID-19 after the vaccine the illness is related to an exposure to an infected individual before adequate immunity was developed.
- 4** According to the clinical trials, both vaccines provide a high level of protection

Vaccine Efficacy	Pfizer	Moderna
After 1 dose	82%	80.2%
After 2nd dose	95%	94.5%

- 5** After receiving the vaccine, healthcare workers must still practice all the same measures to reduce the spread of the virus. According to the CDC, experts are still tracking the protection that the vaccine provides. While vaccinated individuals should not experience signs/symptoms of the illness, it has not yet been determined if it is possible for a vaccinated person to be an asymptomatic carrier of the virus and still spread the illness.

Deciding to receive the vaccine is a personal choice. For additional information about the vaccine the following websites may provide helpful information.

[CDC COVID - 19 VACCINATION](#) | [FDA COVID – 19 VACCINATION](#) | [Local health departments](#) | [State health departments](#)

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# UPCOMING CHANGES TO HIPAA



## UPCOMING CHANGES TO HIPAA NOT SET IN STONE

Last month HHS released a set of proposed changes to the HIPAA Privacy Rule. Anyone can review and submit comments about the proposed changes until March 22, 2021. After that, HHS will review all comments and make any changes they feel are necessary and

issue a final rule that will require compliance. This can sometimes take 90-120 days after the deadline for comments, especially during a year like this when new leadership is in office. Compliance with a final rule is usually required within 60 days after it is published but can sometimes be longer if the changes are complex.

This might mean that we will not see definite changes to the Privacy Rule until late this year, or a required compliance date of early next year.

Thankfully, the theme of the proposed changes is a familiar one. They align with what we have seen other offices under the HHS umbrella doing over the past few years, like the:

- OCR's Right of Access Initiative, that has resulted in increasingly large monetary settlements with covered entities over failure to provide patients timely access to their records.
- ONC's Information Blocking Final Rule, that helps ensure patients have the ability to access their PHI electronically.
- CMS's Interoperability and Patient Access Final Rule, that interacts with the ONC's Information Blocking Final Rule for providers and patients involved in Medicare and Medicaid plans.

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# UPCOMING CHANGES TO HIPAA

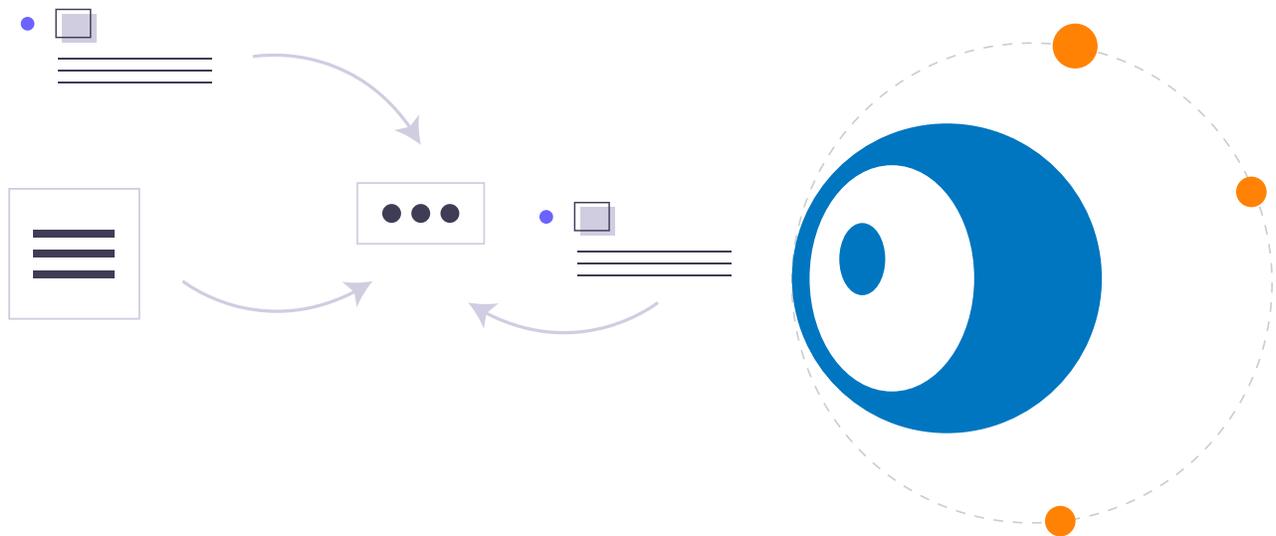
The proposed changes come mostly from the Request for Information posted by HHS in December 2018 that asked for input on how to improve coordination of patient care between unaffiliated healthcare providers as well as patients' right to access their own information.

The timeline to respond to a patient's request for access might be shortened from 30 days to 15 days, with an extension of 15 days instead of the currently permitted 30 days (unless a state or other federal law requires a shorter response time). The Rule clarifies that responses must be made in calendar days, not business days.

Other changes included in the proposed Rule:

- Clarification of fees healthcare providers can charge for patient-initiated access requests, depending on the format requested.
- Requirements of verifying the identification of a person requesting PHI.
- Removal of the requirement to obtain a written acknowledgement of the NPP from a patient, which could be replaced by the right to discuss the NPP with a designated member of the practice.

A few other sections that are frequently reported as barriers to patient care and safety may be modified as well. TMC is closely monitoring this process and is committed to keeping its clients informed and prepared for the changes ahead.



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# ONLINE COMPLIANCE TRAINING

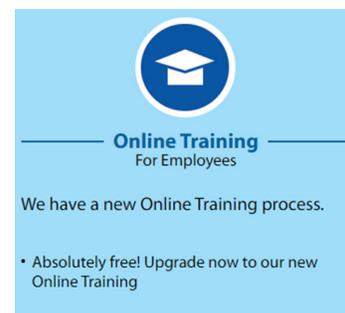


## ONLINE TRAINING TIPS

Last month TMC celebrated the first anniversary of our new online training platform. As we move through 2021, we will be working on ways to continuously improve your user experience. One improvement we have already made is more communications about the changes you can expect to see in our new platform compared to the old platform. Here is a small list of tips and helpful hints we think you will find useful.

### Tips:

- ✓ If you are already a TMC client and have not switched to our new platform yet, log-in to the Client Portal and click the link that reads, “Absolutely free! Upgrade now to our new Online Training” in the blue Online Training box.
- ✓ You will receive a separate username and password for the online training. It will be separate from the user-ID and password that you use to access the TMC Client Portal. You can access both of them at the top of every page on our website.



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# ONLINE COMPLIANCE TRAINING

- **To access the TMC Client Portal** – Click the orange “Client Login” button on the right-hand side of the TMC website.
- **To access the Online Training** – Click the blue “Login to Online Training” button on the left-hand side of the website to access the online training. You must sign up for the new platform before you can log-in.

CLIENT LOGIN

LOGIN TO ONLINE TRAINING

- ✓ If you do not see your Welcome email with your login credentials and instructions, check your junk mail. The email comes from TMC Support <NoReply@totalmedicalcompliance.com>.
- ✓ Your Welcome email only comes to you once. If you forget your username and password, you can request it from your account administrator or our support team at [support@totalmedicalcompliance.com](mailto:support@totalmedicalcompliance.com).
- ✓ If you are the administrator for your online training account, you can add users and track their progress. Remember there can be only one administrator.

Visit our full list of FAQs by clicking [here](#). If you have any other questions, please feel free to contact our online training support team at [support@totalmedicalcompliance.com](mailto:support@totalmedicalcompliance.com)

## IT'S YOUR CALL

### OSHA:

If an employee is exposed to Hepatitis C, how soon after the exposure can infection be detected?

### HIPAA:

Can patients be scheduled for COVID-19 vaccinations using an online or web-based scheduling application?

CLICK HERE  
FOR ANSWERS

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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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