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Adding COVID-19 to the informed consent process: A Q&A for health care providers

As states reopen and health care providers resume their pre-COVID-19 health care activities, there are many new questions. One of the questions on many health care providers' minds is how to minimize their risk should a patient be exposed to COVID-19 while seeking medical care. While implementing effective infection prevention and control practices is the first line of defense for risk mitigation, health care providers should also consider supplementing their informed consent process to include information about COVID-19 risks. Below are some frequently asked questions related to updating the informed consent process.

Should patients be advised of risks related to COVID-19 before obtaining medical care?

While there may be few individuals in the United States today who are not aware of COVID-19, including a discussion of the risk of exposure to COVID-19 in the informed consent process can serve the dual purpose of (1) ensuring patients understand these risks before they consent to receive care, and (2) mitigating the risk of liability to health care providers should a patient allege they were exposed to COVID-19 while seeking medical care from that health care provider.

Legally and ethically, health care providers have an obligation to obtain a patient's informed consent before providing treatment. When informed consent is properly obtained, patients are provided with the information necessary to make informed decisions regarding care. Failure to obtain informed consent can result in liability for the provider.

The applicable statutes, regulations and case law related to informed consent vary by state and type of provider; however, the laws generally require the following:

- A patient must be informed of the material risks and benefits of care;
- A patient must be informed of any treatment alternatives; and
- A patient must acknowledge that he or she accepts the risks in order to receive care.

If one or more of the identified risks occurs, a patient's informed consent can serve as a defense for health care providers who face allegations that the occurrence resulted from the provider's negligence. How courts evaluate claims involving lack of informed consent varies across jurisdictions, but courts generally require that a patient prove that he or she would not have consented to care or treatment if he or she had been informed of the risks.

With respect to COVID-19, including information about the risks of exposure to COVID-19 in the informed consent process can significantly reduce the risk that a patient will prevail in a claim that he or she contracted COVID-19 while obtaining health care services.

What should informed consent for COVID-19 include?

When updating an informed consent process to address COVID-19, health care providers should consider including the following information:

- General information about what COVID-19 is, how it spreads, complications it may cause and difficulties in recovery if the patient has or is exposed to COVID-19 during the treatment process.
- Acknowledgement that social distancing will not be possible in the health care environment.

- Acknowledgement that while precautions will be taken, the patient could still become infected with COVID-19.
- The risks, benefits and alternatives to in-person care, if any.
- Because the understanding about COVID-19 continues to evolve, sometimes on a seemingly daily basis, it would also be advisable to include a statement that all information and risks about COVID-19 cannot be known to the provider.

Should COVID-19 related risks be included in the informed consent in all health care settings?

Each provider must evaluate the need to include COVID-19 related risks on a case-by-case basis. Because of the nature of the virus, risk of COVID-19 exposure is relevant for most, if not all, in-person care settings. However, including information about COVID-19 in the informed consent process would be particularly important for elective procedures or care that could be provided through alternative means (e.g., virtual visits) where patients could reasonably and safely decide to avoid the risk of in-person care.

Should I include a waiver of liability?

Probably not. Waivers of liability are difficult to enforce and can raise ethical issues.

Don't I have immunity from liability from recent legislation?

In certain circumstances, yes. However, immunity protections are limited. Recent federal legislation related to provider immunity is generally limited to COVID-19 specific tests and treatment, or only available for a limited time. For example, the federal PREP Act protects licensed health care professionals who prescribe, administer or dispense "covered countermeasures" such as drugs and devices approved to treat, diagnose, prevent or cure SARS-COV-2 or COVID-19. The PREP Act does not protect against allegations that a patient contracted COVID-19 while seeking non-COVID related medical care and offers no protection against willful misconduct.

At the state level, not all states have adopted immunity protections and among those states that have adopted protections, the scope varies.

Will informed consent protect me from gross negligence?

No. Informed consent may not help a provider who has been grossly negligent such as failing to take standard precautions to prevent the transmission of COVID-19 (which standard precautions are also likely to be required by other relevant governmental agencies and regulatory bodies).

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