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Informed Consent for Urine Drug Testing of OB Patients
Indiana

This summary is for information and education purposes only and does not constitute specific legal advice. OB practitioners should obtain specific legal advice regarding this matter from their own legal counsel prior to making any conclusions or decisions regarding whether to obtain informed consent prior to performing urine drug screening or testing on their patients.

What is informed consent?

The doctrine of informed consent is based on the legal principle of battery, which is the touching of an individual without consent. As such, a medical practitioner may be held liable for a battery for performing any medical procedure that involves a "touching" of a patient where the patient's consent has not been obtained. Generally, a "touching" occurs for any procedure, treatment, surgery, or similar encounter between a practitioner and a patient. Informed consent was further extended based on two concepts: (1) That a patient has the right to determine what happens to his or her body; and (2) That a physician has a duty to provide a patient with enough information to make a decision. As a result, the failure to obtain informed consent was expanded under the common law (meaning decisions by the courts instead of the legislature) to negligence, *i.*e., a physician was found negligent for failing to obtain informed consent.

What are the elements of an informed consent?

The elements of informed consent in Indiana are set in Section 34-18-12-3 Indiana Code and include:

1. The general nature of the patient's condition.
2. The proposed treatment, procedure, examination, or test.
3. The expected outcome of the treatment, procedure, examination, or test.
4. The material risks of the treatment, procedure, examination, or test.
5. The reasonable alternatives to the treatment, procedure, examination, or test.

The Indiana elements follow the recommended elements to be discussed with and disclosed to patients published by the American Medical Association ("AMA") on its website (http://www.ama-assn.org/ama/pub/physician-resources/legal-topics/patient-physician-relationship-topics/informed-consent.page). The AMA's recommended elements include:

1. The patient's diagnosis, if known;
2. The nature and purpose of a proposed treatment or procedure;
3. The risks and benefits of a proposed treatment or procedure;
4. Alternatives (regardless of their cost or the extent to which the treatment options are covered by health insurance);
5. The risks and benefits of the alternative treatment or procedure; and
6. The risks and benefits of not receiving or undergoing a treatment or procedure.

What are the State laws related to informed consent?

The Indiana Informed Consent law at Section 34-18-12 establishes the standard for obtaining informed consent from the patient. Section 34-18-12-4 states, "[t]his chapter does not relieve a qualified health care provider of the duty to obtain informed consent." This implies that for any treatment, procedure, examination, or test, the healthcare provider must obtain informed consent.

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According to Indiana Code 34-18-12-2, informed consent is presumed to have been obtained if the patient's written consent is obtained prior to the treatment, procedure, examination, or test and is: (1) signed by the patient; (2) witnessed; and (3) explained to the patient. The consent is considered "explained to the patient" if the explanation includes the elements listed above.

What is the impact of *Ferguson v. City of Charleston* on provider informed consent?
Ferguson v. City of Charleston was a 2001 case decided by the United States Supreme Court regarding the use of informed consent for urine drug testing of pregnant patients. In *Ferguson*, the Medical University of South Carolina ("MUSC"), the Charleston public hospital, offered to cooperate with the city in prosecuting mothers whose children tested positive for drugs at birth because, despite referrals for counseling and treatment of patients who tested positive for cocaine, the incidence of cocaine use among maternity patients remained unchanged. MUSC worked with police to develop a policy that included, among other things, testing of pregnant patients suspected for drug use. The policy did not include any change in care for prenatal patients who tested positive, nor did it include any special treatment for the newborns. MUSC performed the drug testing without the consent of the patients.

MUSC obstetrical patients who were arrested after testing positive for cocaine challenged the policy claiming that it violated the Fourth Amendment protection against unreasonable searches and seizures. The lower court held that although performing the urine drug test without consent was a search, it was permitted based on prior Supreme Court cases that recognized "that 'special needs' may, in certain exceptional circumstances, justify a search policy designed to serve non-law-enforcement ends." The Supreme Court reversed the lower court ruling, holding that, "[a] state hospital's performance of a diagnostic test to obtain evidence of a patient's criminal conduct for law enforcement purposes is an unreasonable search if the patient has not consented to the procedure. The interest in using the threat of criminal sanctions to deter pregnant women from using cocaine cannot justify a departure from the general rule that an official nonconsensual search is unconstitutional if not authorized by a valid warrant."

The decision to require informed consent from the patient was based on 2 reasons:

1. Because the hospital was a governmental agency, the search and seizure protections of the Fourth Amendment required the patient to consent to the urine drug test.
2. The "special needs" that supported the program do not outweigh the individuals right to privacy in this case because:
    a. The use of positive test results and dissemination to law enforcement was not clearly explained to the patients as a tool to coerce women to obtain treatment; and
    b. The purpose of the test cannot be separated from the state's general law enforcement interest because the test was used to gather evidence for law enforcement and not for patient care, even though the objective may have been to get pregnant woman with positive urine drug screen results into a drug treatment program.

The applicability of this ruling to OB providers in Indiana is limited and does not require informed consent prior to conducting urine drug testing of patients if:

1. The purpose of the urine drug testing is for patient care and treatment;
2. Law enforcement is not involved with the urine drug testing protocol and/or does not receive results of the testing; and
3. The OB provider is not part of a government entity, such as a state or city hospital.

Application and Conclusion

For OB providers in Indiana, a urine drug test would be considered a "test" and would appear to fall within the scope of the informed consent requirement. However, because a urine drug test is not invasive, there is a question whether the generic reference to test includes all tests or only those that are invasive. The rationale that a patient has a right to determine what happens to his/her body supports the argument that the word "test" would only apply to invasive tests and would therefore not include urine drug testing.

Instead, the question of whether informed consent is required would turn on the issue of risk, namely the risk to the patient in performing the test. In performing a urine drug test, there is no physical or medical risk to the patient. The Indiana statute appears to focus exclusively on medical risk. However, an argument could be made that non-medical risks, *e.g.*, potential criminal investigation as in *Ferguson*, must be disclosed to the patient. As such, the question of risk boils down to one question: **"What do you plan to do with the results?"** If the answer to that question is that the results will ONLY be used to provide care to the patient, then informed consent would NOT be required because there are no substantial risks in a urine drug test to identify on the informed consent. Put another way, even if the OB practitioner were to complete an informed consent for the urine drug testing of a pregnant patient, the patient could have a general understanding of the proposed test, the expected outcomes, and possibly the medically acceptable alternatives to the test, but there would be no material risks, medical or otherwise, of the urine drug test.

If, on the other hand, the results might be shared with law enforcement or any other state agency, such as child protective services agencies, then there is an identifiable risk to the patient of which the patient should be made aware through an informed consent. Although it is questionable whether this is legally required, the use of an informed consent in situations where the practitioner would share the results of the test can help protect practitioners from potential legal action.