Best Practices in Clinical Record Keeping: Documenting Informed Consent

Introduction

Documentation of informed consent in the member's chart is important from a number of perspectives: health care ethics, malpractices risk management, and effective member management. The most important goal of informed consent is that the member has an opportunity to be an informed participant in their health care decision making. It is generally accepted that complete informed consent should be obtained from members before carrying out any diagnostic or therapeutic procedure and includes a discussion of the following elements:

- The nature of the treatment plan, procedure or diagnostic testing
- Reasonable alternatives to the proposed intervention
- The relevant risks, benefits, and uncertainties related to each alternative, including the risk of refusing care
- Assessment of member understanding
- The acceptance of the intervention by the member

Ethics

Informed consent is the process by which fully informed members can participate in choices about their health care. It originates from the legal and ethical right each member has to direct what happens to their body and from the ethical duty of the physician to involve the member in his or her health care. Fully informed members have adequate foreknowledge and understanding of the recommended treatment and/or diagnostic testing, the anticipated outcomes, and alternatives to it. It is the process of effectively communicating with members in terms they understand and then allowing them the opportunity to ask questions.

Malpractice Risk Management

Despite our best efforts as careful clinicians to do what is right, bad outcomes do happen. In an informed consent process, the potential risks of an adverse outcome are dealt with up front with each member in a straight-forward and non-threatening manner. Having this conversation with a member first helps a great deal in those few cases with a less-than-optimum outcome. Members who have access to open information exchanges are less likely to claim malpractice.

To protect your patient and yourself in case of malpractice, in addition to carrying adequate liability insurance it is important that communication about the informed consent process itself be documented in the clinical file. Good documentation can serve as evidence in a court of the law that the process indeed took place. A timely and thorough documentation in the member's

chart by the provider of the treatment can be a strong piece of evidence that the provider engaged the member in an appropriate discussion.

Of the complaints that we receive at Heraya, the most common is “the practitioner hurt me.” Often the member goes on to describe an uncomfortable procedure (adjusting, massage, acupuncture needles) followed by post-treatment soreness, stiffness or other symptoms. A complete “informed consent” discussion with that member acknowledging the risk of discomfort with the procedure and the potential of post-treatment soreness may well have prevented this perception and prevented a complaint.

Member Management

Informed members make better health care decisions. Open discussion with members about treatment plans, common alternative treatments that may be available, the risks that may be associated with treatment, including refusing care, and invitation to members to ask questions and receive clarification are primary activities for all health care providers. Often dubbed the “PARQ” conference (an acronym for “procedures, alternatives, risks, and questions”), this open communication empowers each member to obtain all necessary information, ask questions and to collaborate with the clinician in making decisions about care.

Members who are able to make informed decisions are more likely to follow through on your treatment recommendations. They have demonstrably better clinical outcomes, are more satisfied with you and your care and they are more likely to refer their family and friends.

Documenting Informed Consent: “PARQ”

Informed consent is a process involving verbal discussion as well as proper documentation. Heraya recommends as a “best practice” that informed consent be fully documented and included in the clinical file.

One common option for documenting informed consent is noting the acronym “PARQ” which can be written in the member’s chart indicating that the provider has explained the procedures (P), viable alternatives (A), material risks (R), if any, and has asked if the member has any questions (Q). “PARQ” should be noted prior to the implementation of any treatment. If the member requests further information or has specific questions, the provider can underline the PARQ chart notation to reflect the member’s request. The provider should note the particular question and note the more detailed information provided. While this is an appropriate method of documenting that this process has occurred, there is no substitute for the member’s written confirmation of those facts.

It is also recommended that the member execute some document acknowledging that they have been part of an informed consent process, the material risks have been disclosed including a description of those risks and that the member has agreed (“consented”) to the procedures understanding any risks inherent to that procedure. This could be accomplished

using a prepared written consent form that must be signed by the member and should be signed by the doctor. Again, it is important to note that practitioners should not rely exclusively on those forms and must communicate directly with the members.

As new conditions occur that may require different evaluation procedures or different treatment procedures, additional informed consent should be obtained from the member. In addition, consent given to one physician is not consent for any other physician unless the member agrees to the substitute. This assent to the substitute physician should be noted in the clinical record.

THE MINOR MEMBER

As with all members, informed consent is required for minor members. There are different considerations required based on the type of provider delivering the service as well as the services that are being provided. For the purposes of Best Practices, it is recommended that the provider review the specific statutes or rules regarding obtaining informed consent from a parent/legal guardian or the minor members, whichever is appropriate, that applies to the services rendered in the state in which they practice.