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Risk Manager

Medical Assurance Company of Mississippi

Welcome to the latest, and what may be the final, printed issue of the MACM *Risk Manager*! Through some brainstorming sessions with the Marketing Department, we have decided to move away from a biannual printed publication of the *Risk Manager*. Instead, we plan to produce an electronic *Risk Manager* which will be housed on the MACM website and available to you through an emailed link.

Our new electronic publication will be produced three times a year and will feature succinct articles on topics pertinent to your daily practice. We understand your practice and life are busy. We hope this electronic format will be better used by you and easy for you to forward the information to your office staff. We welcome your feedback as we move toward this new format.

In this issue, we are spotlighting informed consent. While this may seem basic to you, the process of gaining permission to perform an invasive procedure or to give a drug with major side effects remains an ongoing concern with MACM claims. Many of the incidents we see in the Claims Department could be mitigated with the proper informed consent process in place. The Risk Management staff has put together a checklist of points to assist you in developing informed consents. Let me encourage you to make this checklist available to every provider in the clinic to use as they develop consents. Please call us if there are any questions.

In follow up to this informed consent checklist, our first electronic publication will feature an article written by MACM Legal Counsel Stephanie C. Edgar, JD. As a former MACM Defense Counsel, Stephanie offers her thoughts on informed consent and the importance this exchange of information can have on the defensibility of a lawsuit.

Your Risk Management consultants are on the road a lot this year. We are scheduled for presentations at conferences and meetings of medical organizations throughout the state. In addition to speaking to medical groups, clinics, and hospitals, we will again host a program specifically geared toward the clinic and office staff. The 2016 MACM Office Staff Program – **Uh Oh! What Do We Do Now?** – will take place in locations throughout Mississippi during the first six months of the year. I hope you have already encouraged and registered your staff to attend. If not, go to the Risk Management page of the MACM website (www.macm.net) and sign up now.

The practice of medicine is not what it used to be. In these trying times in healthcare, your Risk Management staff is here to help you. We will stay up-to-date on the issues affecting our insureds. As always, if there is any way that we in Risk Management can assist you, do not hesitate to let us know.

Sincerely,

Maryann Wee, RN, BSN
Vice President of Risk Management

RISK MANAGEMENT
Enhancing Patient Care • Supporting Physicians

A RISK MANAGEMENT Q&A:
DEVELOPING INFORMED CONSENT FORMS

Questions about informed consent come up quite often in the MACM Risk Management Department. In fact, as part of our resource library we have a template to guide you in developing consents. This consent form template is in Microsoft Word and can be requested by emailing rskmgt@macm.net. Once you receive this information, we encourage you to modify the document to reflect your clinical practice.

To even further assist you, we thought a Q&A would offer some insight into the informed consent process.

Why do I need an informed consent form?

An informed consent form allows you to consistently document the specifics of your discussions about the risks and benefits of your proposed treatment with the patient and/or family. It gives credibility to the fact that you have provided specific information to obtain informed consent if the contents of the discussion with the patient and family are documented on this printed form. When you only dictate or enter this information in the medical record, there is a greater possibility of leaving out important details. And, there is no written signed acknowledgment by the patient included in the chart.

Why can't I use the generic hospital/facility consent form?

There is nothing wrong with using the generic hospital consent form; but, that document alone is not sufficient to protect the physician. The generic hospital form, in the majority of the cases, only states the physician has provided information to the patient but does not outline specifically what was told to them. It is the physician's duty to provide informed consent to the patient, and it cannot be delegated. The staff of the physician may handle getting the form signed by the patient, but it is up to the physician to have the discussion with the patient. It may be necessary for you to negotiate with the hospital/facility to either include your procedure-specific form in the hospital record or to incorporate the details within their consent. For elective procedures, have the discussion with patients, get the signatures on a procedure-specific consent in your clinic, and keep a copy in your clinic medical records. Remember that your consent form will be your best defense in litigation over lack of informed consent.

When is an informed consent form required?

At minimum, an informed consent should be obtained in the following instances:

- Procedures and diagnostic testing;
- Cosmetic procedures or procedures with potential for cosmetic scarring or disfigurement;
- Procedures/medications that affect reproductive system or fertility/fetus well-being;
- Medications that have a black box warning;
- Other situations as appropriate.

What elements should be required in the form?

This is the easy one. Case law from the Mississippi Supreme Court has mandated certain elements that must be included in order for informed consent to occur. These elements are the following:

- Diagnosis
- Name of Procedure/Treatment
- Purpose and Description of the Proposed Treatment – Explain in brief layman's terms what the treatment will accomplish and how it will be done.
- Risks and Consequences of the Proposed Treatment – List the most commonly occurring known risks and how they might affect the patient, including specific further medical care that may be necessary to treat the new problem.
- Risks or Consequences of the Proposed Treatment Specific and Unique to the Patient – Include diagnoses and the complications for which the patient is at higher risk.
- Alternative Treatments – Briefly list other options of care.
- Prognosis if the Proposed Treatment is Not Accepted – Describe what will most likely happen to the patient if the proposed treatment is refused.

How can I start the process of developing consent forms?

- Don't overwhelm yourself by trying to do every form for every procedure at one time. Start with the procedures or medications that are most commonly performed or prescribed in your practice.
- Start with a common format you can adopt for all your consents. Remember, MACM has a template which can be adapted to your practice. Email rskmgt@macm.net to get a copy of our informed consent template.
- As the physician, you should sit down and dictate (or have a staff member write down) what you usually tell a patient undergoing this procedure. We recently sat around a table with an insured using the MACM informed consent format and developed three consents in under one hour. It is important to have physicians actively involved in the process. This is the form that will be your defense against an allegation of failure to provide informed consent. It must accurately reflect your discussion with the patient.
- Don't reinvent the wheel. Google the procedure and see if there is a consent form online or go to a patient-oriented website, such as WebMD, to help you find sample language for your consent. If you do use another source, please be sure you revise it to reflect your clinical practice. It is not the best practice to simply print out a consent developed by someone else. It needs to say what you need it to say — what you routinely tell your patients.

What are some points to remember when developing forms?

- Use simple language – think fifth grade reading level – and define medical terms. A good test for this is to ask a nonmedical staff member to read your draft consent and then review it with you to let you know what was and was not understood.
- Use bullet points rather than long paragraphs.
- Use a font size that is easy to read. An informed consent is not the place for fine print.
- Keep legal language to a minimum. This document is to educate the patient.
- If your consent goes over one page, be sure to number pages, *i.e.* Page 1 of 2.
- Place the date you developed the form at the bottom of the page and periodically review the content to make sure it is still relevant.
- Don't try to have one consent form cover too many procedures. It can be confusing for the patient.

Do we really need consent forms for medication?

We are not advocating consent forms for all the medications you prescribe, just if there is substantial risk. One indicator that a consent form may be needed is if the FDA has a black box warning for the medication. You will want to develop a modified consent form for medications since all the elements do not apply to medication, such as the description of the procedure. But, you do need to include the risks and reasons why it is being prescribed.

Consider utilizing the FDA medication guides that are available on the FDA website at http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm. These can be provided to the patient to supplement the process; but, be sure to document that they were given to the patient. Also, certain medications, such as Accutane, have mandated consents. Be sure you are aware of these.

Are there any other tips about consent forms?

- Don't use the drug or medical device consent forms developed by the manufacturer. These are written to protect and promote the company, not you as the provider. You can, however, use them as a resource to develop your own consent form.
- If you are providing the anesthesia, such as conscious sedation with Versed, include consent for this in your procedure consent form. If general anesthesia is planned, the person administering the anesthesia should have a separate consent form addressing the risks.
- If handouts and videos are used in the consent process, be sure there is a way for the patient to acknowledge he received or viewed these. One option is to include such a statement in the consent form and ask the patient to initial it. Remember to keep copies of the handouts or videos utilized in the consent process so that you can reproduce exactly what the patient was given at a specific time as content will change as you update them.
- Document in the medical record specifically who was present for the entire discussion of informed consent.
- If the patient refuses the procedure or medication, be sure to fully document his refusal.

HOUSTON'S HANDOFFS

By Gerry Ann Houston, MD - Medical Director

An ongoing concern with MACM claims remains the issue of informed consent. While this may seem basic to you, the process of gaining permission to perform an invasive procedure or to give a drug with major side effects continues to be an issue as in the case that follows. This MACM case illustrates the importance of following the correct informed consent process and documenting it in the medial record:

This 59-year-old obese female saw a vascular surgeon for evaluation of a possible pseudoaneurysm following a cardiac cath. At the visit, there was no evidence of an aneurysm at the puncture site. The patient, however, complained of abdominal pain and on exam was noted to have a large ventral hernia. The patient was scheduled for laparoscopic repair the following day.

The surgery was performed, and the patient was discharged after an overnight stay. Over the next few days, she made multiple phone calls to the surgeon with complaints of pain and then a visit to the ED. She was admitted, an evaluation was done, and one week after her initial surgery, underwent a laparotomy with findings of a perforation in the mid transverse colon which required a colostomy along with the bowel repair. Following this, she had multiple office visits, admissions, and surgeries for wound infections and dehiscence. Six months later, her colostomy had been taken down, infections were cleared, and she was released from the surgeon's care.

Two years later, the surgeon received a Notice of Intent to Sue, and two years after that the case went to trial. The plaintiff testified that she was told nothing about the risks of the procedure and certainly nothing about the possibility of a bowel perforation and need for a colostomy. She also claimed that if she had known this she would not have agreed to the surgery. She did sign a standard hospital consent form which specifically said that she had talked with the physician and had been advised of the risks of the procedure. The hospital consent form had a statement for the physician to sign indicating that he had explained the procedure, discussed its risks and benefits, and answered the patient's questions. This part of the consent was left blank; there was no signature of the surgeon. The plaintiff testified she really did not read the consent form before signing it. The MACM physician testified that although he did not document the conversation in the patient's chart, he always describes the procedure to the patient and discusses the risks associated with the surgery. He would include perforation and possible colostomy as part of his discussion.

After a week of testimony, the case went to the jury. The jury rendered a 9-3 plaintiff's verdict in the sum of $390,000 on the basis of lack of informed consent; the vote on surgical malpractice was 6-6.

There was no finding of malpractice in this case. Through the testimonies of the surgeon and the experts for the defense, the jury recognized that a bowel perforation requiring a colostomy was a known and acceptable risk for a laparoscopic hernia repair. What was a problem was the lack of appropriate informed consent.

Though the surgeon more than likely talked with the patient about the procedure and its complications and the expected outcome with and without the surgery, he did not document this in his office record or in the hospital chart. He also did not have a procedure specific consent form that would have listed complications and risks associated with the hernia repair surgery. With these two documents, the patient could not have said she was not told about the risk of bowel perforation and a colostomy, and the jury's verdict would not have been a win for the plaintiff.

INFORMED CONSENT:
PROCESS BEHIND THE PAPERWORK

By Stephanie Edgar, JD - Legal Counsel

Once upon a time, a physician was permitted to act unilaterally on clinical judgments, and all that was required to obtain a patient's consent was the simple affirmation that the patient agreed to be treated. 101 years ago one judge changed the course of American medical ethics by expressly recognizing the patient's dual rights of determination and autonomy. Today, the term "informed consent" is not foreign to any of us. It's batted around incessantly in medical clinics, hospitals, and courtrooms, but I fear, based on examples we've seen, that history may be repeating itself. We've seen this play out unintentionally by physicians that either give so much information that a patient doesn't understand or by physicians that don't give enough information for fear the patient won't understand. Both of these scenarios seem driven, in large part, by a desire to just complete the paperwork and check the proverbial box for informed consent off the list.

Don't misunderstand me - the paperwork is vitally important but only as a memorialization of the process behind it. Informed consent is far more than just a date and signature on a form. Bearing this in mind, your consent process should include simple, easy to understand explanations regarding diagnosis; nature and purpose of the proposed treatment; risks and consequences of the proposed treatment; probability that the proposed treatment will be successful; feasible treatment alternatives; and prognosis if the proposed treatment is not given.

A good rule of thumb is to put yourself in the shoes of your patients. You know medicine. They don't. Otherwise, they wouldn't be in your office. When I was defending physicians in medical malpractice cases and would update clients on their cases, I would on occasion catch myself wanting to use legal terms. The problem with this is that while I knew exactly what I was intending to communicate, I wasn't really communicating at all because the client had no concept of what I meant. So, rather than saying, "we filed an answer on your behalf today," I would say, "we filed an answer on your behalf today, which is just a formal, written response to the complaint that was filed against you."

The same is true in your practice and particularly with regard to informed consent. Take the time to explain in simple, everyday language what's wrong, what you think should be done about it, what might happen as a result of your suggested treatment, what you think the chances of success with your recommended treatment are, other options that are available, and what will likely happen if they don't accept the treatment you've offered. Don't talk at your patients. Talk to them. After you've documented the actual substance of your conversation in the chart and not just the standard, "explained risks and benefits to patient and patient consents", have your patient sign the consent form and make sure to include it in the chart.

Will this process take extra time? Probably. Will it be worth it in the end? Absolutely. Even after doing all of this, can you still be sued for lack of informed consent? Sure, but if you've gone through these steps and you've got the documentation to substantiate that you've gone through these steps, it will be an uphill climb for a plaintiff to prove his case.

Remember that informed consent is more than just a date and signature on a form. It should be an exchange of information that includes instruction as well as time to ask and answer questions so that you have some concept that the patient understands precisely what is being communicated. Rather than just an endpoint, the consent document should be the basis for a meaningful exchange between you, as the physician, and the patient. If you're struggling with the mechanics of the consent process, please contact us. We can walk you through the process step-by-step and assist you in developing consent forms.

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RISK MANAGEMENT STAFF RECEIVE PROMOTIONS

Anne Everett, RN, MSN, has been named Senior Risk Management Consultant. In this position and through the educational services offered to insureds, Everett will continue to work on issues and topics that affect the delivery of healthcare in Mississippi.

Prior to coming to MACM, Everett worked at UMMC in the Adult Emergency Department as an RN case manager. In addition, she worked for Mississippi College as an adjunct nursing instructor. She has a Bachelor of Science in Nursing from Mississippi College; a Master of Science in Nursing from Delta State University; and is currently a Doctoral Student at the University of Southern Mississippi enrolled in the Educational Research and Statistics Doctoral Program, pursuing a PhD with a major in Adult/Higher Education. Everett joined MACM in 2013.

Yevgenia Wilkerson has been named Senior Administrative Assistant. At MACM, Wilkerson will continue to be a resource for insureds working with the Risk Management Department by answering questions and managing the registration for the educational programs offered. She is available to assist office managers and insureds as needed. Having joined MACM in 2014, Wilkerson is also a Certified Professional Coder-Apprentice.