MACM

RISK MANAGER

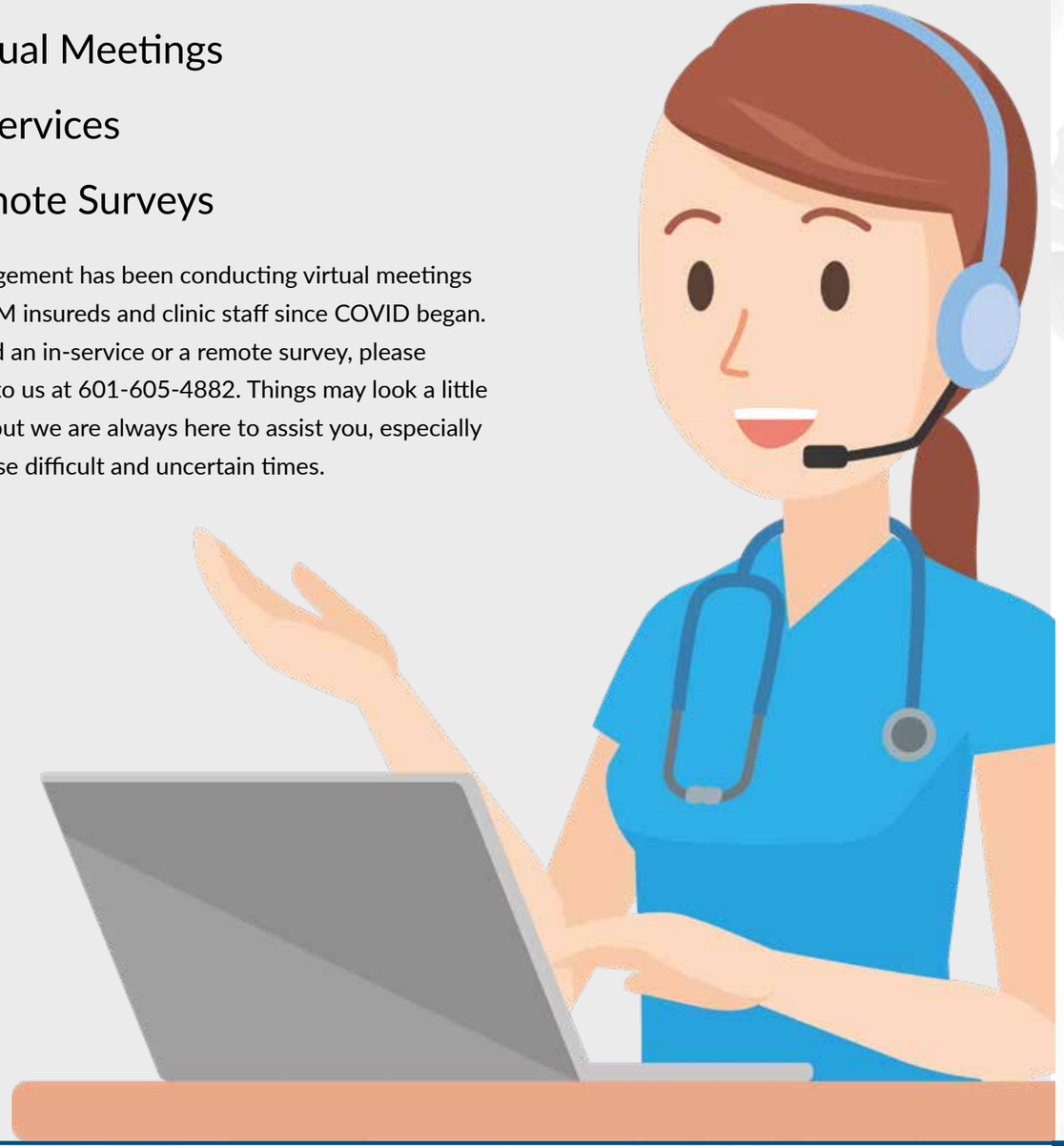
Winter 2020

CONTENTS

DID YOU KNOW WE ARE STILL CONDUCTING BUSINESS AS USUAL?

- Virtual Meetings
- In-services
- Remote Surveys

Risk management has been conducting virtual meetings with MACM insureds and clinic staff since COVID began. If you need an in-service or a remote survey, please reach out to us at 601-605-4882. Things may look a little different, but we are always here to assist you, especially during these difficult and uncertain times.



COVID-19 AND TELEHEALTH:
WHAT ARE YOUR LIABILITIES?

By Stephanie Edgar, J.D., General Counsel

COVID-19 has changed a lot of things, even the way medicine is practiced. As part of the efforts to keep patients safe during this pandemic, telemedicine has been and is still strongly encouraged, regulations have been relaxed, and insurers have begun paying for this service. According to a J.D. Power survey, only 1 in 10 patients used telemedicine services prior to the pandemic. Now telemedicine services such as Amwell are reporting increases of 70-158% in usage.

The Medical Professional Liability Association (MPLA), an international organization made up of companies like MACM, anticipates a rise across the country in telemedicine cases because, of course, as we have more telemedicine visits, there is more potential for cases. They also expect the majority of telemedicine related claims will be due to allegations of failure to diagnose, a delay in diagnosis, and/or failure to refer in a timely manner.

At the urging of MACM, the Mississippi Legislature passed the Mississippi Back-to-Business Liability Assurance and Health Care Emergency Response Liability Protection Act which provides protection to healthcare providers and facilities that have stepped up to treat Mississippi citizens during the COVID-19 crisis. Specifically, the Act states, "Any health care professional or health care facility shall be immune from suit for any injury or death directly or indirectly sustained because of the health care professional's or health care facility's acts or omissions while providing health care services related to a COVID-19 state of emergency." This Act went into effect on March 14, 2020, and expires one year after the end of the COVID-19 state of emergency.

Bear in mind that MACM insureds are only covered to provide telemedicine to patients located within the State of Mississippi. The practice of telemedicine is deemed to occur in the location of the patient. So, if you treat a patient via telemedicine in California, your MACM policy will not apply, and the immunity protections offered by the Mississippi Back-to-Business Liability Assurance and Health Care Emergency Response Liability Protection Act will likewise not apply. Further, you won't get the benefit of Mississippi's cap on noneconomic damages. In addition, you could very well run afoul of licensure boards in other states, which would lead to reciprocal action on your Mississippi license.

Regardless of the legal protections available to you while practicing telemedicine with Mississippi patients, you still must take care to document appropriately and approximate an in-person visit as much as you possibly can. As with anything new, there is a learning curve. In the next article, let's take a look at some lessons learned from providers who are regularly seeing patients via telemedicine.

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By Judy G. Cleveland, BSN, RN, Senior Risk Management Consultant

HOW TO PUT YOUR BEST FACE FORWARD WITH TELEHEALTH

Webside Manner

We all know that bedside manner is an important part of your practice, but now you also need to have a good webside manner. Your usual modus operandi bedside manner may not play as well in a tele-visit, or it may be exactly right. Consider asking for feedback from patients that you know well.

Patient selection and adequate collection of information are the key to a successful telehealth visit. Does the patient have a suitable device and is he in an area with adequate internet access/service? Can the patient easily connect to the visit, and if not, is there someone that can/will be present to assist him? Is the patient's device compatible with the device/service you will be using to contact him?

What about the patient's physical/medical status? Is vision such that the patient will be able to easily see you during the visit? How acute is the patient's hearing? Is he mentally capable of participating in and understanding what happens during the visit, and if not, can/will someone be there to assist?

You may want to come up with a simple list of things that the patient can do on his end before the visit. For example, make sure lighting is adequate so that you will be able to see the patient well. Avoid sitting in front of a window as this can cause issues with visualization. Encourage the patient to decide where he will be during the visit and set up this area ahead of time. Remind him to be in a quiet area away from distractions.

Your name tag or the name on your lab coat should be visible during the visit, or if you have the technical capability, your name could show on the screen. You have the advantage as you know who you are seeing, and you have access to the patient's chart. Not every patient may know you well, and each will need to know who is providing his care.

When the visit starts, ask if there is anyone else there that can overhear the visit and confirm if this is ok with the patient. Document who is present/in hearing distance and the patient's agreement for someone else to listen in.

And know the telemedicine rules and regulations for ALL of the Boards - Mississippi State Board of Medical Licensure, Mississippi Board of Nursing, Mississippi Board of Pharmacy. Check back with them frequently in case the regulations are updated or changed.

Documentation and Consent

First and foremost, you must fully discuss the risks associated with a telemedicine visit and document this discussion. **As the use of a consent form that the patient would sign is not always feasible, the physician should document the consent discussion in the progress note with a statement such as the following:**

> *"As a result of the COVID-19 pandemic, it was determined that this patient met the appropriate criteria for a telemedicine visit in lieu of an in-person visit. The patient was informed of the benefits and limitations of telemedicine including the possibility that the patient's privacy could be compromised despite measures taken to maintain confidentiality and security. Any questions the patient had about telemedicine were addressed. The patient agreed to proceed with the telemedicine visit."*

As this is a medical visit, it needs to be documented as such. Granted you cannot, and should not, document everything as you would in an in-person visit. For example, the physical exam cannot be noted in the same way you would for a face-to-face visit, but you can describe your observations of the patient, e.g. "patient was slumped in the chair and appeared uninterested in the visit", as well as any actions the patient was asked to take in an effort to assess his status. For example, "the patient complained of R shoulder pain that worsened when he was asked to lift his arm to the side".

As with an in-person visit, patients have a right to refuse any and all medical treatment plans or orders. However, the physician can be held liable for patient non-compliance if it is not appropriately documented. At a face-to-face visit, the patient can sign an informed refusal form if he does not wish to follow all or part of your treatment plan. Obviously, in the telemedicine setting, you do not have the option of having the patient sign that he refused treatment; so, if the patient refuses a treatment recommendation during a telemedicine visit, you should fully document what the patient was told as to the importance of and need for the treatment. If the patient still refuses the treatment, then you must clearly document in the visit note the patient's refusal and understanding of the consequences of not following through with the treatment. Be sure to ask and document the specific reason the patient declines such as fear of COVID, etc.

A Few Final Thoughts

This happened fast, and we adapted as best we could, but at some point the COVID-19 situation will be better controlled and the relaxed telemedicine rules and regulations that are currently in effect will be shored up. You need to start addressing this now if your clinic plans to keep the option of telemedicine as part of your daily clinic practice.

Are you truly secure in your ability to perform a physical examination of a patient via telehealth? There are now resources available to assist physicians in becoming more comfortable with examinations of patients via telehealth. For example, some of the premier medical schools in the country have developed short videos which provide alternative methods the physician can employ that incorporate the patient's assistance in performing an evaluation of certain complaints. The American Journal of Medicine recently published, "The Telehealth Ten: A Guide for a Patient-Assisted Virtual Physical Examination" which can be accessed at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7368154/.

Take care not to treat outside your scope of practice and avoid being a Dr. Nice Guy. In other words, if you are a dermatologist, you should not address the patient's hypertension and refill medications in a well-intentioned effort to "help him out".

For the duration of the COVID-19 public health emergency, DEA-registered providers can now use telemedicine to issue prescriptions for controlled substances to patients without an in-person evaluation, if they meet certain conditions. One of these conditions is that the provider must still comply with state laws; so if you prescribe a controlled medication via telemedicine, you must still comply with and document according to Mississippi law related to controlled substances and the regulations regarding prescribing controlled medications from the Mississippi State Board of Medical Licensure.

Telemedicine is not appropriate in every circumstance. You need to recognize when an in-person visit is necessary. The convenience of telemedicine should never override an in-person examination if it is needed. The bottom line is, it's all about doing what is best for your patient.

If a patient refuses a treatment recommendation during a telemedicine visit, the physician should fully document

- Rationale for the recommendation as explained to the patient
- Patient's refusal
- Patient's understanding of the consequences of his refusal
- Reason patient provided for his refusal

CASE STUDY

Case #1

A 46-year-old male was an established patient of an urgent care clinic when he was seen for his annual Healthy You visit in January 2014. At that time, a prostate-specific antigen (PSA) was found to be elevated at 6.71 (normal for his age group = 0-3.5). The defendant physician felt this indicated an infectious process and prescribed an antibiotic. Over the next 12 months, the patient visited the clinic 7 times with various complaints, but a PSA was never repeated. The defendant physician later stated that he had planned to recheck the PSA; but this was not documented in the medical record.

In May 2015, the patient once again presented to the clinic for his Healthy You visit. And, once again, a PSA was obtained and found to have further increased to 12.42. The documentation did not reveal any further examination or plans for follow up or referral. Over the next 12 months, the patient was seen 6 times in the clinic with no documentation of any attempt to address the elevated PSA.

In May 2016, the patient was seen for a Healthy You visit. However, at this time, no bloodwork was obtained, and no exam was documented. The patient returned 5 times following this visit with no further follow up on the elevated PSA.

Two years later in August 2018, the patient self-referred to a urologist for complaint of erectile dysfunction. The urologist documented that a rectal exam revealed the "prostate is firm, large, and irregular to palpation, worrisome for malignancy." An ultrasound of the prostate estimated the weight at 57 grams (normal 20-25 grams). His PSA was now 263.

Two weeks later, the patient underwent a biopsy of the prostate with the resulting pathology report noting an infiltrating prostatic adenocarcinoma grade 7 (Gleason) involving all samples to some degree. Five weeks after the initial visit to the urologist, the patient's PSA had risen to 441.

A metastatic workup was completed which revealed multiple sites of bony metastasis. The patient was referred to oncology and begun on palliative radiation therapy. He expired in February 2019.

The Rest of the Story

The physician recalled that he had offered a digital exam when the first PSA returned as elevated, but the patient refused it. This was not documented in the medical record. According to the clinic staff, phone calls had been placed to the patient advising him of his elevated PSA results and requesting he return for follow up, but he did not return until he had another complaint. The phone calls were not documented in the medical record. The clinic physicians and staff viewed themselves as only providers of urgent/immediate care; therefore, they did not make follow-up appointments for their patients.

Risk Management Issues

The issues in the case were numerous and clearly evident:

- **Failure to diagnose related to a failure to follow up on an abnormal lab result.** This is the most obvious and damaging issue in this case. However, not following up on a test or exam abnormality can sometimes be explained with good documentation of the physician's rationale or the patient's decision.
- **Failure to document the patient's non-compliance.** This can, at times, make or break a medical malpractice case. If a physician offers or recommends a measure that the patient refuses, this should be clearly documented in the medical record.
- **Failure to document phone calls.**
- **Failure to consistently document physical exam findings.**
- **Failure to follow up on previously identified concerns.** It appeared that the physician did not make a habit of referring to earlier visit notes or test results when seeing established patients so that he could follow up on previously identified concerns.
- **Failure to provide a continuity of care.** This clinic was under the mistaken impression that because it was considered an urgent/immediate care clinic, the physicians and staff had no obligation to make follow-up appointments or track screening tests for their patients.

Case #2

A 56-year-old female presented to the defendant gastroenterologist in August 2012. The patient gave a history of adenocarcinoma of the sigmoid colon stage 3B diagnosed in February 2010 for which she underwent a colon resection and was subsequently treated with chemotherapy. Following the August 2012 visit, the defendant gastroenterologist performed a colonoscopy and removed 2 polyps. The patient was scheduled for follow up in 1 year but did not return until November 2014 at which time a repeat colonoscopy revealed another polyp which was removed. The patient was scheduled for a follow-up visit in February 2015 which she cancelled.

The patient was next seen by the defendant physician's nurse practitioner in January 2016 when the patient presented with a complaint of abdominal pain. A CT revealed a pelvic mass adjacent to the sigmoid colon which the radiologist reported as suspicious for malignancy and recommended a colonoscopy for further evaluation. The defendant physician performed a colonoscopy, but it did not show any significant findings. The patient was to return for a follow-up clinic appointment the next month. However, the patient called denying any problems and requesting to cancel that appointment. The NP agreed that the patient could forgo the appointment if she was doing okay. No further work-up was performed, but it was recommended the patient have a repeat colonoscopy in February 2019.

In March 2016 and June 2016, the patient called the clinic on 3 occasions with complaints of pain and diarrhea. She was prescribed antibiotics for probable diverticulitis and Lomotil. The patient returned to the GI clinic in August 2016 with continued complaints of abdominal and pelvic pain. A CT showed hydronephrosis of the left kidney and an enlarging inflammatory mass of the left upper pelvis "suspicious for neoplastic process". A colonoscopy with biopsy of an irregular friable mass at the anastomosis site was not able to confirm malignancy. On September 28, 2016, the patient underwent an exploratory laparotomy during which a large, non-resectable metastatic tumor was found and a loop colostomy was performed. The patient received chemotherapy and radiation treatments in the hopes that the tumor would be reduced to a resectable size. However, the treatments were unsuccessful, and the patient died in November 2018.

The Rest of the Story

The initial colon resection in 2010 did not obtain clear margins. Additionally, the patient only completed approximately two-thirds of her prescribed chemotherapy in 2010 - 2011. She refused to return for the remaining treatments. The defendant gastroenterologist was not aware of either of these issues since he relied solely on the patient's inaccurate description of her medical history rather than requesting records or information from the oncologist and surgeon.

The physician and NP did not believe the medical record accurately reflected their interactions with this patient. The physician stated the patient had been sent several letters imploring her to return to the clinic; however, none of these letters were in the patient's medical record. The staff reportedly frequently spoke with the patient about returning for follow-up which she refused; but these interactions are not documented in the record. Additionally, the NP explained that the patient was frequently rude which is why she reluctantly told the patient that she did not need to return to the clinic following the January 2016 colonoscopy. She was trying to appease the patient; but this is not documented.

Risk Management Issues

- **Delay in diagnosis of metastatic cancer as a result of a failure to adequately explore suspicious findings.** This is the primary allegation. The remaining issues made it difficult to defend against this allegation.
- **Failure to obtain records from other healthcare providers** which may have alerted the physician that the patient's cancer status was more concerning than the patient had stated and may require closer or more in-depth evaluation.
- **Failure to document attempts to contact the patient for follow-up care.**
- **Failure to document the patient's numerous instances of non-compliance.**
- **Failure to document the patient's behavior that led the providers to alter their plan of care** in an attempt to accommodate the patient.
- **Failure to document the rationale for altering the plan of care.**

Summary

These two cases were chosen to highlight common areas of concern that adversely affected the defense of these lawsuits. Several of these topics will be discussed in more detail elsewhere in this publication, to wit:

- clinic systems to track patients who need diagnostic/screening tests or visits
- documentation of the efforts physicians and clinic staff members make to contact and appoint patients for follow-up care and testing
- documentation of education of patients on the rationale for the ordered tests
- documentation of the patient's refusal of the recommended plan of care, including screening tests/visits.

IS YOUR PATIENT'S FEAR OF COVID-19 INCREASING YOUR MALPRACTICE RISK?

By Kathy Stone, BSN, RN, Vice President of Risk Management

You might think it is refreshing for your patients to have concerns about contracting COVID-19. And, indeed, it is better for them to be concerned enough to take appropriate precautions than to dismiss it and conduct business as usual. However, when fear of COVID-19 prevents your patients from accessing medical care, those same patients may ultimately suffer harm they never expected to occur.

A Centers for Disease Control report estimates that 32% of adults in the United States have delayed or avoided routine medical care due to COVID-19 concerns. This would include patients refusing to undergo routine health screenings such as mammograms, colonoscopies and even wellness visits where tests such as prostate-specific antigens may be performed. Indeed, data from United Health Group, Inc. revealed that daily mammograms covered by United Health dropped precipitously in March and April only recovering to the average daily number in July. However, the daily numbers have not increased to make up for the severe lag for those 2 months, meaning many have still not received mammograms that should have.

How are you managing these types of patients? What responsibility do you as a physician have for patients who refuse care? How can you protect yourself from an allegation of malpractice should the patient's refusal result in significant disease, or even death, in the months and years to come?

If you have read the Case Studies in this publication, you have already come to realize that physicians and their clinic staffs do have a responsibility to take appropriate steps to provide screenings and follow-up care, to educate their patients on why screening tests or follow-up care are medically necessary, and to discuss the associated risks of refusing the recommended care.

Screenings During COVID-19

Most clinics have a system in place to track screenings so that the patients can be contacted and scheduled when it is time for the screening. However, COVID-19 has put stress on the usual clinic systems which can lead to a lapse in this tracking system.

You may mitigate the risk of losing track of patients by doing the following:

- **Review and familiarize yourself with the usual tracking system used in your clinic.**

...physicians and their clinic staffs do have a responsibility to take appropriate steps to provide screenings and follow-up care, to educate their patients on why screening tests or follow-up care are medically necessary, and to discuss the associated risks of refusing the recommended care.

As with the Case Studies in this publication, the documentation of informed refusal can be a key component in successfully combating an allegation of malpractice.

Be aware that there may be more than one process in use, especially if different staff members perform this task. Best practice is to have a single clinic-wide system.

- **Discuss the system with the staff that uses it and identify any weaknesses** that might result in inadvertently dropping a patient off the list, especially in cases where the patient wants to postpone the visit or procedure.
- **Develop and implement additional measures to ensure patients who refuse to return for screening are not lost completely** and will be periodically contacted in the future. The responsibility should never be placed solely on the patient to initiate further contact.
- **Encourage your staff to educate the patients on the need for the screening and the risks associated with not undergoing the evaluation.** Prepare the staff by educating them on what you want them to specifically tell the patients. The use of a script for the calls might be appropriate.
- **Send a letter by certified and regular mail explaining the importance of screening and the risks of not having it** and encouraging the patient to contact the clinic to schedule the needed visit/tests.
- **Document all efforts to communicate with the patient, including any letters sent.**
- **Only remove a patient from the screening tracking system at the patient's request, and then only after that patient's physician has approved this action.**
- **Send a letter by certified and regular mail to the patient explaining the rationale for the screening and the risks of not having it, confirming that you have removed the patient from your list, and encouraging the patient to seek the care from another provider.** *Be sure to place a copy of all letters to the patient in the patient's medical record.*
- **Should you choose to withdraw from care completely, please contact the MACM Risk Management Department** for assistance with these delicate situations.

The Risk Management Department frequently works with our insured physicians and clinics in developing good tracking systems. Part of our service to our insureds is the review of clinic policies and procedures and guidance on developing them to minimize patient harm and protect insured physicians and clinics. Additionally, we often review the drafts of letters to patients who are not following the physician's advice. Please call or email us for assistance with this or any other concerns you may have.

Informed Refusal

The term "informed refusal" is not nearly as well-known as that of "informed consent". It is, of course, the opposite side of the informed consent coin. Informed refusal by patients takes place rather routinely in medical practices of all types. How many times have you recommended a medication, procedure, screening test, referral, etc., and had the patient tell you that he was not going to follow your advice, recommendation, or treatment plan? It probably happens almost daily. Yet, it is rarely documented, or it is documented inadequately.

As with the Case Studies in this publication, the documentation of informed refusal can be a key component in successfully combating an allegation of malpractice. Let's look at the dual aspects of informed refusal.

First, there is the expectation that the patient will be informed of the medical reasons for the treatment plan. This is simply patient education that is provided routinely by physicians and staff members in every medical practice. However, it does not always get documented adequately – or at all. Neglecting this documentation step means you are not giving yourself credit for the care you are providing. Patient education is a necessary part of medical care which often gets overlooked when a caregiver is documenting, or it is simply noted with a templated statement that is meaningless and not patient specific.

When documenting patient education related to the patient's refusal to comply with your desired treatment plan, be sure to document

- **Specific treatment, medication, referral, test, etc., that was recommended/ordered**
- **Rationale for the recommendation/order**
- **Short statement of how you explained it to the patient in terms the patient can understand – include the worst possible outcome as a result of the patient's refusal**
- **Patient's reason(s) for not complying with the plan**
- **Any attempts you have made to accommodate or address the patient's reason for refusal.**

Having dealt with the "informed" portion of informed refusal, let's discuss the "refusal" aspect. Patients, of course, have a right to refuse any and all medical treatment plans/ orders. However, the physician can be held liable for patient non-compliance if it is not appropriately documented. It is certainly acceptable to document the patient's refusal in the medical record alone, as described above. But, to further solidify documentation that the patient knowingly refused your recommendation or order, you may opt to have the patient sign an Informed Refusal Form. You may obtain a sample of this form by contacting the Risk Management Department.

The MACM Risk Management Department has recently begun adding an Informed Refusal section at the end of our procedure and medication specific consent forms as we develop them. This makes it very easy to document the patient education on the need for the procedure or medication as outlined in the consent form while also getting the patient's signature and date on the refusal section of the form.

If it is not feasible to have the patient sign a form, you may choose for two staff members or you and a staff member to call the patient to confirm the patient's refusal. The documentation in the medical record of the patient's refusal would then note the name and title of the person who witnessed the conversation.

During the COVID-19 pandemic, physicians and clinics should be cognizant of the need to document a patient's refusal to return for screening exams or tests, since many patients are postponing this type of medical care. Documentation should also include all of the efforts by the clinic staff to periodically communicate with those patients in order to schedule the screening visits/ tests, as discussed earlier.

During the COVID-19 pandemic, physicians and clinics should be cognizant of the need to document a patient's refusal to return for screening exams or tests, since many patients are postponing this type of medical care.

In summary, physicians should clearly document the instances in which a patient refuses to comply with their treatment plan whether it is for a medication, procedure, screening, referral, or any other type of medical care. In so doing, the physician provides a clear and thorough description of her assessment and plan while simultaneously creating a record that speaks to the physician's care and concern for the patient's well-being – both of which will serve the physician well should she be faced with a malpractice claim or lawsuit.

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PRACTICAL SUGGESTIONS FOR YOUR PRACTICE DURING THE COVID-19 PANDEMIC

Some of the following recommendations have probably already been implemented by many of you while others may be new. The less common, but no less significant, recommendations have been highlighted for your convenience.

- Stay in touch with staff and providers regarding personal issues
- Develop staffing plans for employee absences and illnesses
- **Stay informed – visit local (ex. Mississippi State Department of Health) and Centers for Disease Control websites often**
- **Designate a compliance officer to monitor regulatory developments**
- Anticipate medication shortages
- Discontinue the use of toys, magazine, and other shared items
- Instruct all staff and patients to wear facemasks. Provide masks to patients as needed
- **Become familiar with mental health resources. Consider adding a mental health screen to your visits due to an increase in home abuse/violence**
- **Document all patient interactions, regardless of mode of communication, in the patient's record (summarize them if they cannot be imported)**
- **Implement tracking systems for follow-up and track screenings such as colonoscopies and mammograms, as well as diagnostic tests**