CNA NSO HPSO

Risk Management Strategies for the Outpatient Setting

Risk Management Strategies for the Outpatient Setting

Legal and Regulatory Risks

Contents

Definitions

A few basic definitions are provided to ensure a baseline understanding of the terminology utilized in the following sections.

Potential compensable event (PCE) is characterized by an unanticipated adverse event or medical error causing an injury or clinical sequelae. Indications of a formal claim may or may not be present. However, based upon the nature of the incident, injury and litigious patient/family communications, there is a likelihood that a claim will be initiated.

Incident typically refers to an event that is not in alignment with customary operations and/or policies and procedures of the outpatient healthcare setting and is reported through internal channels. The event may or may not be associated with a patient injury. An incident also may be associated with a medical board complaint, an unanticipated adverse event or a request for medical records.

Claim is a verbal or written demand for compensation based upon an alleged error or omission resulting in injury or damage and may be filed as a lawsuit or pre-suit notification. A demand may be made in writing, in person, or by telephone, facsimile or email. It may be asserted informally in the form of a letter or telephone call (often directly from the patient), or formally submitted as a filed legal action. Claims may be asserted by the patient, the patient's guardian or a family member with appropriate legal authority.

A **subpoena** is a court order issued by attorneys, government agencies or courts requiring an individual to appear in court, or other legal and regulatory proceedings, and testify. A subpoena also may require document production.

A **lawsuit** is a civil legal action initiated by filing a complaint within the judicial system. Lawsuits are governed by the rules of civil procedure. When a lawsuit is filed by a patient, a Summons and Complaint will be filed with the court and delivered by the designated authority to the named parties or the defense attorney, if one has already been assigned.

Professional Liability Claims: Prevention and Management

Not all unanticipated adverse events result in a claim or a lawsuit. Prompt, proactive management of these events enhances patient safety and may reduce the likelihood that a claim will be initiated. Providers and staff should collaborate with risk managers and become active participants in preventing claims, while simultaneously enhancing defensibility in the event a lawsuit is filed.

The role of the risk manager and clinical leaders in preventing and/or managing claims varies among outpatient healthcare settings. However, customary risk management activities relating to claim management include, but are not limited to, the following:

- Reporting PCEs to regulatory bodies and insurers, as required.
- Conducting the initial investigation following a PCE.
- Documenting investigational activities and correspondence related to the event.
- Ensuring the integrity of the patient healthcare information record and securing other pertinent documents, equipment and information associated with the event.
- Organizing claim files and coordinating activities with insurers and the defense team.
- Reporting potential and actual claim activity to professional liability insurers through appropriate channels.
- Trending and analyzing the organization's adverse event and claim data to support the development of risk management initiatives and prevent future occurrences.
- Benchmarking and reviewing industry liability trends. CNA publishes claim reports that provide additional information and detail on professional liability claims and licensing board actions focusing on healthcare practitioners including dentists, pharmacists, nurses, nurse practitioners, physical therapists, and counselors.

Although we cannot predict with certainty when an adverse event or medical error will result in a claim, the following are often precipitating factors:

- Diagnostic error coupled with serious harm and/or adverse financial impact.
- Anger or distrust.
- Retaliation for billing disputes and collection actions.
- Lack of communication with provider(s) regarding outcome and future care.
- Unrealistic expectations regarding treatment outcomes.
- Inaccessibility of provider(s) after an adverse event.
- Altruistic reasons, i.e., "I don't want it to happen to someone else."

Identification of the above risk factors, including proactive risk management techniques, may help to reduce the likelihood that a patient will pursue a claim. For example, training providers on how to effectively communicate with patients and families after an unanticipated adverse event may help to reduce a patient's anger and distrust towards providers.

Occasionally, providers may become so distraught about a medical error or serious adverse event that they isolate themselves from the patient and family. This reaction results in emotional distress for the provider and also creates a chasm in the provider-patient relationship, often leading to the pursuit of legal action as a last resort. Peer support programs may help providers resist the instinctive "flight" response. In addition, coaching sessions may be offered to help providers navigate difficult disclosure conversations.

Medical Malpractice

Malpractice is a type of negligence. It is often referred to "professional negligence." Malpractice claims in the outpatient healthcare setting are often related to a failure or delay in diagnosis, improper management of test results and referrals or improper performance of a procedure. Communication issues and a lack of clear expectations regarding treatment outcomes also may influence a patient's decision to file a claim or lawsuit.

Parties to a malpractice lawsuit involve the following:

- Plaintiff(s) – parties who initiate a lawsuit in a court. Such parties may include a patient, family member or third party.
- Defendant(s)–the parties against whom a claim or charge is brought in a court.
- Witness(es)-individuals who provide additional information regarding the case and sequence of events, including experts, consultants, staff, and organizational leaders, among others.

In order to prevail in a medical malpractice lawsuit, all of the following 4 requirements are met:

1. The provider owed a duty to the patient.
2. There was a breach of duty (standard of care).
3. An injury was sustained.
4. There was a direct causation between the breach and the injury sustained.

Establishment of the Provider-Patient Relationship

Determining if a provider owes a duty to the patient depends upon whether a provider-patient relationship exists. Providers may be held liable even if they believe no provider-patient relationship was established. It is incorrect to assume that an individual is not a "patient of record" if the patient was only seen on one or two occasions or never accepted a treatment plan. Irrespective of the circumstances under which it is created, including location of provider or duration of the contact, a provider-patient relationship may be deemed to have been formed. For example, a provider may offer professional information or opinion establishing a provider-patient relationship, even when the communication occurs outside of a professional practice setting. If the patient suffers an injury as a result, the provider may be held liable.

The legal existence of the relationship is a question of the facts specific to each individual case. Any of the following factors may indicate that a provider-patient relationship exists:

- A contract is executed between the provider and patient.
- A history is taken and/or physical examination is performed.
- An entry is made into the patient healthcare information record.
- A bill for services is sent.
- A medical consultation was provided.
- The patient receives care from the provider.

Standard of Care

A medical malpractice lawsuit is based upon allegations that a provider failed to properly fulfill the "standard of care." Standard of care violations relate to the professional conduct of a reasonable provider in the same jurisdiction with similar credentials. This judgment will be based upon the standard that existed at the time the care was rendered.

In a malpractice lawsuit, the standard of care is articulated through the testimony of expert witnesses. Expert witnesses are professionals with background and training similar to the defendant, typically from the same practice community, who give their opinion to the court regarding the allegations in the complaint. Expert witnesses retained by the plaintiff opine as to why the defendant's care failed to meet the standard, and that the failure was the direct cause of the injury. Defense attorneys also will retain expert witnesses to refute the plaintiff's allegations.

Another factor to consider when determining the standard of care is educational curricula, including what is taught both in medical and other healthcare professional schools, as well as continuing education courses. If a provider uses unapproved procedures, materials, or techniques, whether the standard of care was fulfilled may be scrupulously analyzed.

Resolution of Claims and Lawsuits

Claims and lawsuits may be resolved, by a settlement between the parties, through mediation or arbitration, by a jury verdict at trial, or by the plaintiff's voluntarily dismissal of the lawsuit against one or more defendants. It may take years before a malpractice suit reaches trial. Insurance policies vary with respect to the management of settlement decisions. There may be a consent to settle clause, which requires that an insurer obtain its insured's consent before settling a claim. In non-consent to settle policies, the insurer collaborates with the involved provider(s), but ultimately has the final decision making authority regarding settlement determinations. An insurer's decision to settle a claim or lawsuit is based upon several factors, including the assessment and apportionment of liability, estimated likelihood of prevailing at trial, as well as an assessment of how the witnesses will appear during testimony before a jury.

Managing Claims and Other Legal Notices

Diligent management of actual and anticipated claims and/or lawsuits can reduce the potential severity of the matter. Attempting to manage claims and other legal notices independently will be counterproductive to the defense. The professional liability insurer must be notified immediately, and defense counsel assigned, so that they may respond on behalf of the outpatient center and/or involved provider. Designation of a staff member of the outpatient setting to handle legal notices will ensure prompt notification to insurers and seamless coordination of required responses.

Upon receipt of notification from a patient asserting a claim of injury, or when a summons and complaint or subpoena has been received, the following steps should be taken:

- Immediately report the matter to the professional liability insurer of the outpatient facility and/or provider(s) involved in the situation.
- Secure all medical records, equipment and evidence that may be important to the defense of the case.
- Do not discuss the facts of the case with the patient or any party other than the professional liability insurer and the attorney representing the outpatient facility and/or involved provider(s).
- Respond immediately to requests for information by the insurance carrier and attorney representing the outpatient facility or provider(s).
- Refer all inquiries for information involving the case to the attorney representing the outpatient facility or provider(s).
- Copy and retain the summons and complaint, subpoena and attorney letter(s) for your records.
- Maintain signed and dated copies of all employment contracts.

Reporting to Your Professional Liability Insurance Carrier

Professional liability insurance policies include provisions to guide insureds on how and when to report potential compensable events (PCEs), claims and lawsuits in order to comply with the policy terms and conditions, and initiate a prompt investigation. Refer to your claim professional or broker for specific details regarding the protocol for claim reporting. In situations where a formal claim notice has not been received, but there is reason to believe that that a claim will be initiated, such as when an attorney's request for records is received or the patient verbally indicates dissatisfaction with care or the plan to file a claim, the insurer or broker should be notified. The insurer will evaluate coverage, initiate an investigation and assign a defense attorney, if indicated.

Typically, a written summary is included in the initial report addressing details of the PCE, claim or lawsuit including, but not limited to, the following:

- How, when and where the adverse event took place;
- The names and addresses of any injured persons or witnesses; and
- The nature and location of any injury or damage arising out of the occurrence.

In addition to the initial report of a claim, pertinent documents, including policies and healthcare information records, are typically included in the initial notification.

Subpoenas

In the context of a medical malpractice lawsuit, a plaintiff attorney may issue subpoenas to named defendants or other treating providers who are not named in the lawsuit, but may be utilized as witnesses. The subpoena is a court order requiring providers or the outpatient facility to submit evidence in court and/or to produce documents, such as paper copies of the electronic health-care information record or policies in effect at the time that care was rendered.

Subpoenas are delivered in person or by certified mail. Deadlines for responding to subpoenas and penalties for non-compliance with the subpoena apply. It is imperative that you consult with legal counsel and your professional liability insurer immediately upon receipt of a subpoena so that they may respond on your behalf. Attempting to manage these requests on your own may be counterproductive in defending your case, if you are a named party, or may potentially result in you or your facility being named in the lawsuit

State Licensing Board Matters

For state licensing board matters, such as licensure restrictions, disciplinary matters, or complaints filed by patients or others, consult your professional liability insurer and/or legal counsel to obtain guidance prior to initiating a response. Matters such as these often emanate from allegations of professional misconduct, fraudulent billing or scope of practice violations. It is important to emphasize the benefits of concise, objective documentation in the healthcare information record, as this may help to avoid a lengthy licensing board investigation. Insurance coverage for legal expenses related to state licensing board complaints varies depending upon the insurer, policy, exposures, and jurisdiction, among other factors. Many professional liability insurance policies will provide defense coverage related to these matters.

Managing the Risks of Vicarious Liability

Healthcare organizations or provider-owned outpatient facilities and practices may be held vicariously liable for the negligence of employees acting within their scope of practice. The following suggestions may help to minimize vicarious liability risks:

- Review your professional liability insurance policy to determine whether it includes vicarious liability coverage.
- Require a certificate of insurance from all independent contractors.
- Ask independent contractors sharing space to sign a hold harmless/indemnification provision, which minimizes exposure against any losses arising from their activities. As these clauses are varied and complex, consult with legal counsel before initiating or signing any contracts.

Apparent (Ostensible) Agency

Vicarious liability is not limited to liability resulting from the actions of employees. It also may arise from the actions of individuals with whom the provider has, *or appears to have*, a supervisory relationship. Vicarious liability involves the legal theory of apparent agency, also referred to as ostensible agency. The theory of apparent agency applies, for example, to independent contractors (IC). An outpatient healthcare organization or physician group practice may be held liable for the acts of independent contractors if the patient believes that the independent contractor was acting as an employee of the organization or practice.

Therefore, an important liability consideration is whether the patient had a clear understanding of the independent status of the IC. If the patient perceived that the contracted provider was associated with the healthcare organization or group practice, the IC may be deemed to be an "apparent agent." For healthcare business owners, well-drafted contracts relating to independent contractors, as well as ensuring clear role delineation and provider employment status, may help mitigate liability in lawsuits claiming vicarious liability.

National Practitioner Data Bank

The National Practitioner Data Bank (NPDB) or "the Data Bank" was created by the *Health Care Quality Improvement Act of 1986* and operates within the U.S. Department of Health and Human Services. It's important for healthcare providers to be aware of its role.

The Data Bank was created to serve as a flagging system to facilitate a review of healthcare practitioners' professional credentials. The information contained in the Data Bank is used by healthcare entities, state licensing boards and professional societies, in connection with information from other sources, for decisions involving clinical privileges and credentialing, employment, affiliation, or licensure. Healthcare providers, entities, and suppliers are permitted to self-query and/or dispute information reported to the NPDB. Refer to the NPDB guidebook for a complete list of providers who are authorized to query.

Each insurance company or other entity that makes a malpractice payment for the benefit of a practitioner must submit a report if the payment meets certain criteria. The companies also are required to send these reports to state licensing boards. Each state licensing board also establishes its own reporting requirements.

Informed Consent

Informed consent (IC) is a two-way educational and communication process that provides patients with sufficient information to make a reasoned decision regarding proposed treatment. The consent must be given without coercion or fraud, based upon the patient's reasonably accurate and complete understanding of what will take place. The IC process is a legal and ethical obligation, serving to enhance decision-making and protect both parties.

Although some practitioners may consider the informed consent process burdensome and time-consuming, it is critical to effective risk management. Providers who ignore the wishes of a patient and proceed with treatment without the necessary consent may be subject to malpractice litigation, whether or not the treatment was in the best interest of the patient in the provider's professional opinion. If the treatment can be characterized as an unauthorized touching of the patient, the provider also may have committed the criminal offense of battery.

Most patients have a reasonable idea of procedures that occur during routine examinations or treatment. Thus, patients are sometimes considered to give implied permission for treatment when they visit an office for routine care. Implied consent, however, is limited as a legal defense.

Fundamentals of Informed Consent

The informed consent process involves two primary components:

- **Discussion**, including disclosure and patient education.
- **Documentation in the healthcare information record**, which typically includes the use of a written informed consent form.

The informed consent discussion represents the first step in managing patient expectations, thus reducing the possibility of a misunderstanding and a consequent lawsuit. In addition, documentation of the informed consent process provides the best defense against a patient's assertion that the proposed treatment, other options and the potential for complications were not adequately explained.

Many claims of professional negligence are accompanied by an allegation of lack of informed consent. In such an action, patients may assert that, if they had known in advance that an adverse outcome was possible, they would not have agreed to the treatment. Rarely do claims solely allege lack of informed consent, without other claimed damages.

In many lawsuits, the provider met the standard of care, but the patient was dissatisfied with the outcome, often due to a lack of communication. A sound informed consent process can enhance patient management and education, thus reducing risk.

Informed consent is a process, not a specific document. The process requires a verbal component, irrespective of whether a written form is used. In most jurisdictions, a patient can give an oral informed consent. However, informed consent requirements vary among states, and a written form may be required in addition to discussion with the patient. Whether the patient's permission is spoken or written, the goal of the informed consent process remains the same: to ensure that the patient has an adequate understanding of the proposed treatment, including its risks and alternatives, as well as the consequences of no treatment, prior to giving consent.

Although laws and regulations vary, most states require that patients be given sufficient information on three major subjects:

1. **Nature of the proposed treatment**, including the need for treatment, its anticipated benefits and the prognosis.
2. **Alternatives to the proposed treatment** including an explanation of the risk and benefits associated with the alternatives, as well as reasons that the recommended care is preferable to other options, such as specialty referral or no treatment.
3. **Foreseeable risks**, including potential complications of the proposed treatment and the risks of refusing it. Similar to the discussion of alternative treatments, the list of foreseeable risks need not be all-inclusive, but it should reflect the patient's condition and overall health status.

In addition, if medical residents, interns, fellows or medical supply vendors will be present at and/or participating in a proposed surgery or procedure, their presence and roles should be disclosed to the patient, including in the IC discussion and documented in the patient healthcare information record.

Following the educational component of the consent discussion, patients should be asked whether they have any questions about the proposed treatment or any other information given to them. The patient then states his/her desire to either pursue or decline the proposed treatment. Questions and answers and the patient's decision should be noted in the patient healthcare information record.

The provider who will perform the treatment or procedure must conduct the IC discussion – it cannot be delegated. Nurses and other healthcare staff may witness a patient's signature on a consent form, but they are not permitted to conduct the informed consent discussion. IC rules vary as they pertain to nurse practitioners, certified nurse midwives, certified registered nurse anesthetists and other non-physician providers. Refer to state statutes and regulations, as well as professional licensing board guidelines, ethical opinions, and healthcare legal counsel for specific guidance on the IC process in these cases.

Informed Consent Tips

The following strategies can help enhance the informed consent process:

- **Tailor discussions** to the needs and level of understanding for each patient.
- **Use basic, uncomplicated language** that the patient can understand, defining any technical terms that must be used.
- **Consider the complexity of the proposed treatment and the degree of risk** when conducting the informed consent discussion with the patient.
- **Focus on the educational opportunity that IC provides.** Use brochures, as well as pamphlets, models and other educational resources, as needed.
- **Give the patient opportunities to ask questions**, and answer as clearly and comprehensively as possible.
- **Ask the patient to "teach-back" and describe the proposed plan of treatment** in his or her own words.
- **Encourage the patient to have a family member present in the room** during the IC discussion to make the patient feel more at ease.
- **Have a staff member present during the IC discussion** to serve as witness.
- **Be aware that in most cases, minors must obtain the consent of a parent or legal guardian** prior to beginning treatment. Many states allow for an exception to obtaining parent or legal guardian consent when the minor is seeking treatment for sexually transmitted disease, pregnancy, and birth control. An emancipated minor can also seek treatment without the consent of parental or legal guardian.
- **Always ask the patient, "Do you have any questions about the information you have been given or about the proposed treatment?"** and document the answer.
- **If necessary, use a qualified interpreter**, noting their name, address and telephone number in the patient healthcare information record. Interpretive services can be for language as well as communication barriers including, but not limited to, hearing and visual impairments. Family members and friends should not serve as interpreters unless the clinical situation is emergent and a qualified translator in unavailable. In that event, document the reason for using a family member/friend and the patient's consent to do so.
- **Consider translating standard consent forms** into commonly spoken foreign languages in the area serviced.
- **Proceed only after obtaining the patient's approval**. Any treatment rendered without the patient's consent may result in malpractice allegations or charges of battery.

Informed Refusal

Every adult patient with decision-making capacity has the legal right to decline treatment recommendations. At the same time, the physician or other healthcare provider is responsible for clearly explaining the reasons for pursuing the recommended course of care, as well as the potential consequences of not doing so. Patients who experience serious injury after refusing care may later assert that their provider was negligent in failing to fully disclose the risks of forgoing treatment. The patient may further assert that if the risks of refusal had been properly and completely explained by the provider, he or she would have consented to the procedure or treatment.

The following risk control measures, adapted to the unique needs and circumstances of individual practices or facilities, can help healthcare providers and organizations reduce liability exposures relating to refusal of treatment:

- Create a standard informed refusal form that accompanies and documents the provider-patient discussion. (See sample form provided in this section, which should be modified as necessary.)
- Inform the patient that refusal of treatment may affect progression and treatment of other medical conditions, and note this discussion in the patient healthcare information record.
- Continue to examine and treat the patient for the duration of the provider-patient relationship, periodically noting in the healthcare information record that the patient continues to decline the recommended treatment and is aware of continued risks associated with this refusal.

Documenting informed refusal. Refusals of care increase liability exposures, which can be minimized by comprehensively documenting the informed refusal process and emphasizing that the patient understood and acknowledged the risks of rejecting the recommended care.

Techniques for documenting informed refusals are similar to, but surpass, those for informed consent. After discussing the potential consequences of refusal with the patient, write a comprehensive progress note and document the refusal using a written form, which should be incorporated into the patient healthcare information record.

Progress notes should document:

- Those present during the discussion.
- The treatment discussed.
- The risks of not following treatment recommendations, listing the specific risks presented.
- The brochures and other educational resources provided.
- The questions asked and answers given by both parties.
- The patient's refusal of the recommended care.
- The patient's reasons for refusal.
- The fact that the patient continues to refuse the recommended treatment.

Using an informed refusal form. Few patients remember all that they were told during the informed consent/refusal discussion, making written forms a valuable reminder. A written form also helps manage patient expectations, provides further documentation of the disclosure of information and may deter negligence claims. The informed refusal documentation process is not designed to persuade reluctant patients to accept necessary and recommended treatment. It serves as an additional communication process to ensure the patient understands the risks they are accepting with their refusal of the recommended treatment or procedure.

Obtaining Informed Consent Under Special Circumstances

Under certain circumstances – such as when the patient is a minor, is cognitively impaired or is undergoing a life-threatening emergency – the process of obtaining informed consent (IC) becomes more complex. In such situations, risk management representatives and legal counsel should be consulted regarding relevant state statutes and regulations. Their input should be documented in the patient's healthcare information record, including other relevant medical and treatment details.

Pediatric patients. Before rendering treatment to an unemancipated minor, providers must first obtain the IC of a parent or legal guardian. Adult siblings, grandparents and other adult caretakers are generally authorized to provide consent only if they have been granted legal guardianship by the court. If a parent or legal guardian cannot be contacted by telephone, determine the degree of urgency as indicated by presenting signs and symptoms, and then decide whether to proceed immediately or defer treatment until consent can be obtained. Document the factors considered in the patient healthcare information record.

Adolescents. Minors cannot consent to their own treatment unless they are emancipated. Laws vary across the United States on what constitutes emancipation and there is little guidance provided from federal law. Therefore, you must be aware of state specific guidance on criteria to be an emancipated minor. In general, emancipated minors are considered those who serve active duty in the military, minors who are married, or minors living independently from their parents and managing their own financial affairs. If an unemancipated adolescent presents for care and is unaccompanied by a parent or legal guardian, the following steps can help minimize potential liability exposure:

- **Make a reasonable effort to contact a parent or legal guardian.** Document all such attempts – whether made by telephone, text message, email or other means – in the patient healthcare information record.
- **If a parent or legal guardian cannot be contacted immediately, defer routine treatment** until a parent or guardian has been informed of the patient's situation and has authorized care.
- **If immediate intervention is imperative due to traumatic injury or other emergent conditions, provide necessary care to the patient** while continuing efforts to contact the parent or guardian. The patient healthcare information record should include the rationale for proceeding with emergency care, as well as ongoing efforts to obtain authorization.

Cognitively impaired patients. For patients to grant their informed consent to or refusal of treatment, they must have the capacity to comprehend the relevant issues. Therefore, if there is reason to doubt a patient's decision-making ability, the provider must assess his or her capacity in this area. Patients who can respond cogently to the following three requests are generally considered capable of giving consent to medical treatment:

- **Describe the reason for your visit/admission to the facility,** including major symptoms and concerns.
- **In your own words, repeat back what we have discussed** about your condition and treatment needs.
- **Tell me a little about yourself,** such as your age, birth date, address and name of an emergency contact person.

Emergency situations. The majority of states recognize special circumstances where delaying treatment in order to obtain IC may be detrimental, such as an emergency situation when the patient is unable to give consent and efforts to contact a family member or guardian have been unsuccessful. In addition, the IC process can be modified if, in the provider's judgment, full disclosure of risks would have a serious adverse effect on the patient or the thera-peutic process. For example, a depressed patient who may potentially become actively suicidal if given too much information during a mental health crisis represents a situation in which the IC process may be modified.

Special cases such as these may present a high degree of both stress and risk for healthcare providers. For this reason, facilities and practices should hold regular training sessions about the IC process, with attention paid to consent issues involving patients who are minors, are cognitively impaired and/or are experiencing a life-threatening emergency.

Informed Consent Documentation and E-consent

The patient's informed consent must be documented in the healthcare information record, including evidence that the patient understands and agrees to the proposed treatment. A written description of the informed consent discussion, signed and dated by the patient, effectively demonstrates that the process has been completed. Consult state laws and regulations to determine whether a written informed consent document is required, but even if it is not mandatory, a written form serves as valuable documentation of the consent process.

Irrespective of whether a written informed consent form is used, write a progress note that reflects the specific consent process for the patient, including questions asked and answers given, staff and/or family members present, educational materials provided, and whether the patient agreed to or declined the recommended treatment.

Sample Discussion and Consent for Treatment/Procedure Form

Patient's name: *(Last, First, Middle initial)* _____ Date of birth: _____

I am being provided with this information and consent form so I may better understand the treatment/procedure recommended for me. Before beginning treatment/procedure, I wish to be provided with sufficient information, presented in a form that I can understand, to make a well-informed decision regarding my proposed treatment/procedure.

I understand that I may ask any questions I wish, and that it is better to ask them before treatment/procedure begins than to wonder about these issues after treatment/procedure.

Nature of the Recommended Treatment/Procedure

It has been recommended that I have the following treatment/procedure: _____

_____

This recommendation is based upon physical examination(s), diagnostic test results and my doctor's knowledge of my medical history.

My needs and desires have also been taken into consideration. The treatment/procedure is necessary due to _____

_____

The intended benefit(s) resulting from this treatment/procedure is (are): _____

_____

The prognosis, or likelihood of treatment/procedure success, is: _____

_____

Alternative Treatment/Procedure

The treatment/procedure recommended for me was chosen because it is believed to best suit my needs. I understand that alternative methods or treatment/procedure options include: _____

☐ No other reasonable treatment/procedure options exist for my condition.

_____ I have had an opportunity to ask questions about these alternatives and any other treatment/procedure that I have heard or thought about, including: _____

Patient's initials

_____

Risks of the Recommended Treatment/Procedure

I understand that no treatment/procedure is completely risk-free and that my provider will take reasonable steps to limit any complications. I am aware that some treatment/procedure effects and complications tend to occur with regularity. These include:_____

_____

_____ I have had an opportunity to ask questions about these and any other risks about which I have heard or thought.

Patient's initials

(continued)

Acknowledgment

I have provided as accurate and complete a medical and personal history as possible, including antibiotics or other medications I am currently taking, as well as those to which I am allergic. I will follow any and all treatment/procedure and post-treatment/procedure instructions as explained to me and will permit the recommended diagnostic procedures.

I realize that notwithstanding the possible complications and risks, my recommended treatment/procedure is necessary. I am aware that the practice of medicine is not an exact science, and I acknowledge that no guarantees, warranties or representations have been made to me concerning the results of the treatment/procedure.

I, _____, have received information about the proposed treatment/procedure. I have discussed my treatment/procedure with _____ (specify provider), and have been given an opportunity to ask questions and have them fully answered. I understand the nature of the recommended treatment/procedure, alternative options and the risks of the recommended treatment/procedure.

My signature below indicates that I understand the risks and wish to proceed with the recommended treatment/procedure.

Signature of patient or guardian: _____ Date: _____

Signature of treating provider: _____ Date: _____

Signature of witness: _____ Date: _____

This sample form is for illustrative purposes only. Your clinical treatments/procedures and risks may be different from those described. We encourage you to modify this form to suit your individual practice and patient needs. As each practice presents unique situations and statutes may vary by state, we recommend that you consult with your attorney prior to use of this or similar forms in your practice.

Sample Refusal of Treatment/Procedure Form

Instructions

This form should be signed by the patient or authorized party if he/she refuses any surgical procedure or medical treatment recommended by his/her physician or provider. If the patient or authorized party not only refuses the treatment/procedure, but also refuses to sign this form, note this fact in the patient healthcare information record.

1. I have been advised by my physician/provider *(insert name)* _____, that the following treatment/procedure should be performed upon me *(insert name of treatment/procedure):* _____

   _____

2. Nature of the Recommended Treatment/Procedure

   This recommendation is based on physical examination(s), diagnostic test results and my physician's/provider's knowledge of my medical history. My needs and desires have also been taken into consideration. The treatment/procedure is necessary due to:

   _____

   The intended benefit(s) resulting from this treatment/procedure is (are): _____

   _____

   The prognosis, or likelihood of treatment/procedure success is: _____

   _____

   The consequences of not proceeding with the recommended treatment/procedure are: _____

   _____

3. Alternative Treatment/Procedure *(check one):*

   ☐ The treatment/procedure recommended for me was chosen because it is believed to address my medical condition. I understand that alternative treatment/procedure options include: _____

   _____

   ☐ No other reasonable treatment/procedure options exist for my condition.

4. I have read the following educational materials provided to me *(list materials, if applicable):*

   _____

5. Risks of Not Having the Recommended Treatment/Procedure:

   I understand that complications to my health may occur if I do not proceed with the recommended treatment/procedure. These complications include: _____

   I have had an opportunity to ask questions about these risks and any other risks I have heard or thought about.

6. Acknowledgment

   I, _____, have received information about the proposed treatment/procedure. I have discussed my treatment/procedure with my provider/physician and have been given an opportunity to ask questions and have them fully answered. I understand the nature of the recommended treatment/procedure, alternate treatment/procedure options, and the risks of the recommended treatment/procedure, and my refusal of care.

7. My reason for refusal is as follows: _____

(continued)

8. I personally assume the risks and consequences of my refusal, and release for myself, my heirs, executors, administrators or personal representatives those physicians/providers who have been consulted in my case as well as *(insert name of medical practice)* _____, its officers, agents and employees, from any and all liability for ill effects that may result from my refusal to consent to the performance of the proposed treatment(s)/procedure(s).

I acknowledge that I have read this document in its entirety, that I fully understand it and that all blank spaces have been either completed or crossed off prior to my signing.

I do NOT wish to proceed with the recommended treatment/procedure.

Signature of refusing patient: _____ Date: _____ Time:_____ ☐ AM ☐ PM

Signature of refusing party, if other than the patient: _____ Date: _____

Relationship to patient: _____

Signature of the physician/provider: _____ Date: _____

Signature of witness: _____ Date: _____

This sample form is for illustrative purposes only. Your clinical treatments/procedures and risks may be different from those described, We encourage you to modify this form to suit individual needs of your healthcare setting and patients. As each setting presents unique situations and statutes may vary by state, we recommend that you consult with your attorney prior to use of this or similar forms in your healthcare setting.

For more information, please call us at 215-509-5437 or visit www.nso.com or www.hpso.com.

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