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Introduction

Informed consent is the process of a provider and a competent patient discussing treatment or an intervention and where the provider discloses appropriate information that is meaningful to a patient and enables the patient to make a voluntary choice to accept and consent to or decline the treatment or intervention.

Deconstructing this definition requires:

- Provider and patient acknowledging that informed consent is a process and not an executed document.
- Provider comprehension of the distinction between capacity and competency. Capacity is a clinical assessment and competency is a legal declaration. Capacity can be fluid.
- The distinction between informed choice and informed consent. Consent is informed if the competent patient can voluntarily make an informed choice. This process requires discussion of the risks & benefits of the treatment/intervention/procedure and the risks & benefits of alternative options. Informed choice includes expectation management.
- All of this requires provider comprehension of what is meaningful to the patient. This requires discussion of values and trade-offs from the patient perspective and clearly defining the decision alternatives, ramifications and consequences from the both the provider and the patient point of view. This discussion should include financial implications for the patient, if possible
  o Recent surveys have demonstrated that patients want their providers to include the cost of the decision with their recommendation, if possible.
  o If the patient has financial concerns and the provider cannot provide this information, the provider may recommend that the patient and the office manager contact the insurance company.
- A patient’s voluntary choice to agree/accept the treatment/intervention/procedure results in agreement/acceptance with the informed consent document and authorization to proceed.

There are three components in this deconstruction: legal, ethical and clinical. The following graphic defines the elements in each of these three components:
Informed consent is a process of communication and the consent form should provide evidence of this process. The focus is the process, not the signature. **The role of the provider in the informed consent process is to facilitate the patient’s decision making.**

**Why is consent necessary?**

This question seems elementary, but in addition to the obvious reason for consent, so that the patient is informed and can therefore make a decision; consent is necessary to meet compliance mandates. Compliance with survey or accreditation organizations include state survey agencies, CMS, The Joint Commission (TJC), Det Norske Veritas Healthcare, Inc (DNV) and Healthcare Facilities Accreditation Program (HFAP).

In order to participate in and receive federal payment from Medicare or Medicaid programs, a health care organization must meet the government requirements for program participation, including a certification of compliance with the health and safety requirements called Conditions of Participation (CoPs) or Conditions for Coverage (CfCs), which are set forth in federal regulations. The certification is achieved based on either a survey conducted by a state agency on behalf of the federal government, such as the Centers for Medicare & Medicaid Services (CMS), or by a national accrediting organization,
that has been recognized by CMS (through a process called “deeming”) as having standards and a survey process that meet or exceed Medicare’s requirements. Health care organizations that achieve accreditation through a deemed status survey are determined to meet or exceed Medicare and Medicaid requirements.

The Joint Commission’s focus is on safe, quality care through a voluntary independent evaluation process. TJC considers itself a performance improvement organization above and beyond its deeming status role.

The Det Norske Veritas Healthcare’s purpose is safeguarding life, property and the environment.

The Healthcare Facilities Accreditation’s purpose is to advance high quality patient care and safety through objective application of recognized standard.

CMS identifies the goals of informed consent practices: transparency, autonomy, safety, beneficence and respect. CMS asserts: “Current regulations holding hospitals accountable for informed consent (CMS COP; the joint commission; state laws), while well-intended, fail to ensure patients receive reliable written information about the procedure.”

CMS has created measures for informed consent document quality to align with national strategies to promote patient-centered decision making.

CMS advises that although comprehensive informed consent documents enhance patient comprehension and satisfaction, they are seldom given to patients early enough or with sufficient detail and explanation to encourage their involvement in formulating their care plans.

The Hospital Inpatient Quality Reporting Program was originally mandated by Section 501(b) of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003. This section of the MMA authorized CMS to pay hospitals who successfully report designated quality measures a higher annual update to their payment rates.

Under the Hospital Inpatient Quality Reporting Program, CMS collects quality data from hospitals paid under the Inpatient Prospective Payment System, with the goal of driving quality improvement through measurement and transparency by publicly displaying data to help consumers make more informed decisions about their health care. It is also intended to encourage hospitals and clinicians to improve the quality and cost of inpatient care provided to all patients. The data collected through the program are available to consumers and providers on the Hospital Compare website at: https://www.medicare.gov/hospitalcompare/search.html.
Data for selected measures are also used for paying a portion of hospitals based on the quality and efficiency of care, including the Hospital Value-Based Purchasing Program, Hospital-Acquired Condition Reduction Program, and Hospital Readmissions Reduction Program.

CMS assesses the quality of each informed consent document for persons enrolled in Medicare for service Part A and is 18 years of age or older and having a qualifying elective procedure based on whether it meets the following criteria:

- Is language describing “WHAT is the procedure” (beyond the medical name provided for the patient?)
  - If provided, is it typed?
- Is a description of HOW the procedure will be performed provided for the patient?
  - If provided, is it typed?
- Is the clinical rationale for WHY the procedure will be performed provided?
- Is any patient-oriented benefit provided (e.g., intended impact on patient’s health, longevity, quality of life)
- Is a QUANTITATIVE probability provided for any procedure-specific risk?
- Is a QUALITATIVE probability provided for any procedure-specific risk?
- Is any alternative provided for the patient?
- Was the informed consent document shared with the patient at least one day before date of procedure? If not, identify whether the patient opted out of signing the consent in advance.

**When is consent necessary?**

Consent is recommended for all treatments, interventions and procedures. Recognizes that there are always exceptions that relate to the practicality of this recommendation. For example, the outpatient environment often has high frequency procedures that may not necessitate a consent.

Consent is necessary for photographing a patient for scientific/educational/research purpose or for follow up. Specific consent must be taken if the identity of the patient is likely to be revealed while publishing.

Specific consent is necessary for photography.

Consent is necessary for participation in clinical trials and research projects.

**Type of consents**

*Hospital and physician practices*

Hospital consents are more general and physician practice consents are more specific. Hospitals generally do not provide procedure-specific information (risk, benefits and alternatives) and expect that physicians will provide this specific information.

Hospital consents do not protect the physician who is performing the procedure.
Informed Consent

Elements of consent

Informed consent process and documents have state specific mandates and guidelines. The state specific laws and regulations should be reviewed and incorporated into the process and document.

The provider performing the procedure must be credentialed and appointed as a member of the medical staff of the facility.

The elements of consent include:
- The condition/disorder/disease that the patient is having/suffering from
- Necessity for further testing
- Natural course of the condition and possible complications
- Whether the procedure is diagnostic or therapeutic
- All procedures to be performed, including foreseeable or possible procedures that may be necessary based on intraoperative findings
  - If procedures are foreseeable, be as specific as possible rather than using language providing consent to a procedure based on the provider’s clinical judgement.
  - General language providing consent to a procedure based on the provider’s clinical judgement is appropriate only for unanticipated and emergent procedures
- In cases where there is a rule-out-diagnosis or a working diagnosis or when there is diagnostic uncertainty, these should be identified along with identifying the procedure options
- Identifying the risks of the procedure
  - General risks
  - Serious risks, up to and including death
  - Common risks
  - Probability, magnitude of risk: include low or high frequency of risk occurrence and severity of risk (for example, “frequency of occurrence risk is statistically low (define percentage), but the outcome of the risk is serious and includes ________”
- Identifying the benefits of the procedure
  - General benefits
  - Preventative effect
  - Survival increased
  - Comfort increased
  - Ability to evaluate prognosis
- Alternatives/Other options
  - General alternatives
  - Specific alternatives
  - No treatment as an alternative
    - Consequences of non-treatment
- If a medical device will be implanted, identify the risks, benefits and alternatives
- Duration and approximate cost of treatment or financial implications to patient if known.
- Expected outcome
• Follow-up required
• Statement indicating the patient has the right to refuse/decline treatment or refuse/decline treatment after consenting
• Statement on how the patient could obtain further information
• Statement of what the patient could do if they did not understand the information
• Statement of disclosure if provider or facility has a financial interest in the treatment/therapy or intervention
• Statements indicating whether there was a structured decision making process including expectation management
  o Some providers use a decision worksheet that provides talking points to lead the patient and provider through the decision making process
  o The steps in the structured decision making process:
    ▪ Framing (what am I deciding)
    ▪ Alternatives (what are my choices)
    ▪ Meaningful, reliable information (what do I know)
    ▪ Clear values and tradeoffs (what consequences do I care about?)
    ▪ Logically correct reasoning (am I thinking straight about this?)
    ▪ Decision/commitment
  o These worksheets generally contain statement options that relates to how involved the patient wants to be in the decision
    ▪ The patient wants to make the decision together with the physician
    ▪ Clear emphasis on the patient wanting extensive information and the physician providing an opinion, but ultimately the decision is the patient’s
    ▪ The patient wants the physician to decide
• Dating and timing of the form:
  o If the surgical consent is a paper form that is scanned into the medical record after all signatures are documented, then manual dating and timing is required. Omitting manual dating and timing is a frequent CMS survey deficiency
  o Tablet or electronic forms are automatically dated and timed when the patient signs the form
• If interpreter is necessary, the documentation should include the printed name, signature and date of the interpreter

Determining adequacy of information discussed with the patient
The patients' perception of risk of a medical intervention is highly individualistic, variable and unpredictable.

There are three recognized standards to assess the value of the information provided to the patient to enable an informed choice and consent:
• **Reasonable provider standard**: what would the average provider determine to disclose and discuss. In other words, what would a reasonable practitioner, in the same or similar circumstances tell the patient about the risks and benefits of, and alternatives to the procedure to obtain the patient’s consent
Research indicates that the average provider has minimal discussion and therefore this standard may not be adequate. Additionally, this may be a paternalistic model and does not factor in the values of a specific patient.

**Reasonable patient standard**: what would the average patient need to know to make an informed decision

- There have been court decisions declaring that a provider’s training and experience may be a material consideration for the patient as an element in their decision process on whether to undergo the procedure with the provider
  - However, disclosing experience in terms of success or failure rate may breach peer review privilege
  - Training and experience may be considered “personal characteristics”. This can become a slippery slope, as examples of other “personal characteristics” identified by patient plaintiffs in informed consent cases include treatment for substance abuse, prior license sanctions, etc. Courts have handled the reasonableness of this type of disclosure in different ways.
  - It is recommended that “personal characteristics” disclosures be reviewed to determine if they are material for a patient to make a decision and whether there has been any state precedent set.

**Subjective standard** for specific patient

- The provider should explore tradeoffs vs values
- The provider should explore the patient’s beliefs and goals that influence their decision-making
- The provider and patient should discuss how involved does the patient want to be in the decision-making process
- Informed consent templates are discouraged

In court, when a standard is based on “reasonableness”, it requires the jury to determine what should have been done, discussed or disclosed. This means that in an informed consent case, each juror will decide what they would have wanted to be told about the procedure. This weighs the standard toward more disclosure. In effect, the jury weighs whether they, themselves, would have desired more information vs whether the patient’s demands for more information were unreasonable.

**Exceptions to disclosure**

There are three traditionally recognized exceptions to disclosure:

- **Therapeutic privilege (also known as therapeutic nondisclosure)**: If a provider is of the opinion that certain information can seriously harm a patient's health, related to physical, mental or emotional well-being, the provider has the privilege to withhold such information.

  Therapeutic privilege has been recognized by some courts and is supported by scientific literature. The AMA *Code of Medical Ethics* says that physicians may withhold information about a patient’s diagnosis or treatment when disclosing it would pose a serious psychological threat, so serious a threat as to be medically contraindicated. Competent patients retain the right to
refuse treatment and must be given as much information as necessary to help them make informed decisions about consent or refusal.

- Example: A patient with the diagnosis of delusional parasitosis which is a mistaken and unshaken belief that parasites have infested the body: Many times these patients seek out multiple providers who rule out real parasite infestation and advise that the patient has a psychiatric condition. The patient does not accept the psychiatric diagnosis and seeks out more providers. In this situation, patients are often seeking providers who believe them and the patient wants prescriptions for antibiotics, antipariticities or antipruritic topical creams.

Therapeutic privilege is applied when the provider withholds the diagnosis and instead advises that the patient has stress which is contributing to the condition. If stress is addressed and relieved, then the situation will improve over time. The provider then refers the patient to a psychiatrist for the diagnosis of stress. The provider will tell the psychiatrist the actual diagnosis and that therapeutic privilege was invoked.

In this situation, the patient is not incompetent, but because of the delusion, the patient's decision-making capability is impaired. This is known as decisional incapacity and is addressed in the section “Capacity and Competency”. With decision incapacity, the patient will not be fully capable of making health care decisions as the illness itself prevents understanding of the diagnosis.

Withholding the diagnosis which carries the stigma of psychiatric illness may be preferable to insisting that the patient hears the actual diagnosis which may result in the patient not seeking the treatment that is needed. If the patient does not seek this treatment, the situation would not improve and harm may result. Additionally, insisting on the patient hearing the diagnostic name of delusional parasitosis may be viewed as causing “iatrogenic suffering”. Iatrogenic suffering is a result that is not related to the disease or diagnosis and has been caused by the provider.

- Another example of withholding a diagnosis as a therapeutic privilege and which may cause a problem: There are times where a patient may have an important event to attend and this coincides with “bad” medical news (diagnosis or prognosis). The bad news will likely negatively affect the event and providers may elect to withhold the bad news until after the event. If a provider withholds the bad news until after the event, the patient may feel deceived or feel grateful. Here the therapeutic privilege is clearly a paternalistic action which must be individualized to the patient and balanced with the fact that the patient is competent and does not have a psychiatric condition that would impair decision-making.
The rationale for withholding information should be clearly and comprehensively documented. The use of therapeutic privilege must be justified based on danger and/or patient incompetence.

Therapeutic privilege cannot be used as a way to attain consent and it cannot be used to avoid giving bad news.

- **Placebo**: The deceptive use of placebos is generally considered not ethically justifiable. However, there are specific and rare exceptions and could be considered under the following conditions:
  - The medical evidence concludes that the intervention is known to have a high placebo response rate
  - The alternative intervention options are ineffective and/or present significant risks
  - The patient has a strong need for an intervention
  This should be clearly and comprehensively documented in the medical record.

- **Patient declaration**: If the patient advises the provider of their preference to not be told the truth and instead abdicates their role in decision making to a surrogate, the provider has a duty to discuss the implications of this abdication.
  - If the patient chooses to make an informed decision not to be informed of the elements of informed consent, the provider should respect this decision.

### Exceptions to full consent

- If patient lacks capacity: locate surrogate decision-maker
  - If no appropriate surrogate decision maker is available, providers are expected to act in the best interest of the patient until a surrogate is found or a guardian ad litem may have to be appointed by the court.
- If patient lacks capacity and it is an emergency: In this situation consent can only be presumed and is not obtained. Emergency situations are generally limited to preventing death or disability.
  - If the patient is incapacitated and is in a critical care unit, implied consent does not apply to all treatment or procedures.
- If patient lacks capacity and has an advanced directive, a living will, a Do Not Resuscitate (DNR) document or a Physician Order for Life Sustaining Treatment (POLST)
- If patient lacks capacity and has appointed a durable Power Of Attorney for health care decisions

### Consent to procedures when patient is a DNR

Issues can arise when a patient signs a DNR and then codes during a consented-procedure. The code could be caused by the patient’s diagnosis or the code could be a result of iatrogenic error. Research reveals that if the code was caused by iatrogenic error, a majority of providers will override a DNR order.
and resuscitate. The research provides two arguments provided for overriding a DNR order after iatrogenic error: providers feel guilty and/or providers were unaware of the DNR status.

In this instance, the issue is whether a provider’s need to feel better by providing a particular treatment (resuscitation) should override the patient’s autonomous right to refuse that treatment.

If the provider/code team honors the patient’s wishes for DNR, they may face allegations of an iatrogenically caused death. If they provide CPR, they may face a negligence suit alleging iatrogenic error, the failure to know the patient was DNR, the override of the patient’s stipulated wishes, and a possible suboptimal outcome if the patient is intubated in the ICU.

Proactively resolving this dilemma requires the consent to address whether the patient wants resuscitation in the event of an iatrogenic error. The mention of harm from medical error in an informed consent or informed refusal conversation is unusual and not seen in industry practice. Therefore it cannot be considered a “best practice”. Additionally, because error is not supposed to happen and should not happen if the provider is complying with the standard of care, one cannot require providers to disclose it as a “reasonable” risk.

This issue should be discussed within the organization as a possibility. It interlaces medical error with liability, guilt feeling and ethical obligations.

Consider the following:
When a patient’s preferences regarding an iatrogenic cardiac arrest have not been discussed, the patient’s consent to DNR status offers the best evidence of the patient’s autonomous preference not to undergo this invasive intervention. Providers should therefore respect the patient’s DNR status, even when the cause of the arrest is iatrogenic.

**Continuing responsibilities after consent has been signed**

Consent forms must be maintained in the office records and in the hospital or outpatient clinic medical records.

Consent forms must be reviewed in the preoperative area before any medication has been administrated. This seems obvious, however studies have concluded that a high percentage of paper consent forms are misplaced or lost which results in delays and revenue loss, patient dissatisfaction, having to obtain consent in a hurried environment which may lead to miscommunication and issues with expectation management. The consent review should be documented in the patient medical record.

Review of the consent form for verification of right patient/procedure/surgery site is the most effective mechanism for avoiding wrong patient, wrong procedure and wrong site surgery.
**Duration of informed consent**

In general, informed consent is valid for the course of the treatment. If there has been a significant change in the plan, condition or diagnoses, a new consent process and form is required.

As stated above, under the “CMS” section, CMS provides that the patient’s signature must be obtained at least one day before an elective procedure or it must be noted that the patient opted out of viewing the informed consent document at least one day prior.

There are no authoritative rules that express how far in advance a consent should be obtained/executed. Since the purpose of consent is to have a conversation that results in informed consent, the earlier the conversation takes place will enable the patient and physician to have a thoughtful and detailed conversation. There are some sources that cite claim reviews of cases alleging inadequate informed consent and report that there are higher indemnity and legal expenses when consent forms are executed in the preoperative holding area instead of the surgeon’s office.

**Informed consent and research**

The HHS regulations state that “An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence” (45 CFR 46.116). This requirement applies to all nonexempt human subjects research not eligible for a waiver of the consent requirements.

*Coercion* occurs when an overt or implicit threat of harm is intentionally presented by one person to another in order to obtain compliance.

*Undue influence* occurs through an offer of an excessive or inappropriate reward or other overture in order to obtain compliance. Non-financial incentives can also influence a subject’s decision to consent to research. For example, the subject/patient may perceive undue influence by feeling obligated to participate in research if their physician is also the investigator.

The Institutional Review Board (IRB) is tasked with determining whether circumstances give rise to undue influence.

Additional elements necessary during the informed consent process (See 45 CFR 46.116(b))

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable
- Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent
- Any additional costs to the subject that may result from participation in the research
• The consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject
• A statement that significant new findings developed during the course of the research which may relate to the subject’s willingness to continue participation will be provided to the subject
• The approximate number of subjects involved in the study

Capacity and competency

Capacity refers to an assessment of the individual's psychological abilities to form rational decisions, specifically the individual's ability to understand, appreciate, manipulate information and form rational decisions. If the physician evaluates a patient and determines that the patient lacks capacity, then the patient is referred to as de facto incompetent, i.e., incompetent in fact, but not determined to be so by legal procedures.

Competency is a legal term and is determined by a court. Competency is a broad concept encompassing many legally recognized activities, such as the ability to enter into a contract, to prepare a will, to stand trial, and to make medical decision. The definition, therefore, must be clarified depending on the issue in question. Competency refers to the mental ability and cognitive capabilities required to execute a legally recognized act rationally.

The ethics literature further defines capacity related to decisions as “decisional capacity” and characterizes this as dynamic. An individual can have decisional capacity on one day and not on another day. These dynamic situations occur when there are reversible causes of impaired decisional capacity which includes intoxication, hypoxia, stress or sedation. The literature also suggests that capacity level is decision specific.

The determination of decisional capacity has practical application challenges and also may be challenged by the patient, family members or surrogate decision makers. If the provider believes and determines that a patient does not have decisional capacity, the provider will have to define the decision as urgent or non-urgent. If the decision is urgent, the provider will be required to seek consent from the surrogate decision maker, as defined in the patient’s estate planning documents.

If the patient has not appointed a surrogate decision maker, the provider will have to make the decision that is in the best interest of the patient. All of this process and rationale should be documented in the patient’s medical record.

If the patient does not have decisional capacity, as determined by the provider, and the decision is not urgent; the provider will have to identify the cause or source of the dynamic or fluid incapacity and treat the cause/source.

The patient does not have the capacity to provide informed consent or informed refusal/declination when intoxicated. Diagnosis of intoxication is determined by the legal limit of intoxication (known as legal intoxication) in the jurisdiction and not by observation.
However, alcohol tolerance is individualized. A person who has a long history of using alcohol may have a high tolerance level and not be clinically intoxicated at the same time that they are legally intoxicated. This should be documented, but because the patient is legally intoxicated, the patient does not have capacity.

If the patient’s blood alcohol level is under the legal limit but appears clinically intoxicated, this too, should be documented and considered when making a capacity assessment. It is possible to not be legally intoxicated and not have decisional capacity.

The following diagram provides a decision-making process for the provider to use as a guideline when the patient has decisional incapacity.

The provider has a legal duty, a professional responsibility and an ethical obligation to respect patient autonomy, provide a safe environment, do good (beneficence) and do no harm (non-malfeasance). Navigating duties, responsibilities and obligations require balancing of risks and benefits from both the patient and provider perspectives.

Informed consent with patients having low health literacy, learning disorders or Limited English Proficiency (LEP)
Patients having low health literacy, learning disorders or limited English proficiency (LEP) should have specific documentation in both the consent form and the medical record that is customized.
The US Department of Health and Human Services defines health literacy as the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions. Health literacy includes numeracy skills and requires knowledge of health topics.

The Agency for Healthcare Research and Quality (AHRQ) states that only 12% of U.S. adults have the health literacy skills needed to manage the demands of our complex health care system, and even these individuals' ability to absorb and use health information can be compromised by stress or illness. The AHRQ provides a tool kit that is evidence-based and offers guidance to adult and pediatric practices to ensure that systems are in place to promote better understanding by all patients.

The Agency for Healthcare Research and Quality and the National Institutes of Health both offer comprehensive information, guidance and tools to assist providers.

The National Assessment of Adult Literacy (NAAL) provides examples of health literacy levels:

<table>
<thead>
<tr>
<th>Health Literacy Level</th>
<th>Task Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proficient</td>
<td>Using a table, calculate an employee’s share of health insurance costs for a year</td>
</tr>
<tr>
<td>Intermediate</td>
<td>Read instructions on a prescription label, and determine what time a person can take the medication</td>
</tr>
<tr>
<td>Basic</td>
<td>Read a pamphlet, and give two reasons a person with no symptoms should be tested for a disease</td>
</tr>
<tr>
<td>Below Basic</td>
<td>Read a set of short instructions and identify what is permissible to drink before a medical test</td>
</tr>
</tbody>
</table>

Some insurance carriers have software that can analyze a document and identify complicated and industry words and phrases and then provides suggestions for replacements. The goals of this software are to provide information in plain language and to improve the readability of the document. Plain language is defined by the federal government as communication that users can understand the first time they read or hear it. With reasonable time and effort, a plain language document is one in which people can find what they need, understand what they find, and act appropriately on that understanding.

In July, 2016, the Affordable Care Act finalized Section 1557: Ensuring meaningful access for individuals with limited English proficiency (LEP). This section defines covered entities as any health program or activity, any part of which receives funding from the Department of Health and Human Services (HHS), such as hospitals that accept Medicare or doctors who receive Medicaid payments; the Health Insurance Marketplaces and issuers that participate in those Marketplaces; and any health program that HHS itself administers.

Section 1557 requires covered entities to:
1. Post a notice of individuals’ rights providing information about communication assistance for individuals with limited English proficiency
2. Post taglines in the top 15 languages spoken by individuals with limited English proficiency in that state that indicate the availability of language assistance
3. Requires covered entities to utilize qualified translators
4. When machine translation is used, entities are required to ensure that a qualified translator has reviewed the translation
5. In instances when a communication is particularly long or complicated, covered entities may now be required to provide a written translation of the communication or an audio file for the patient to refer back to

Section 1557 prohibits:
- The use of untrained staff and interpreters when providing language assistance
- Prohibits organizations from requiring LEP patients to provide their own interpreter
- Prohibits the use of minor children as interpreters
- The use of low-quality video remote interpreting services.

Covered entities are encouraged to develop and implement a language access plan.

Organizations should be prepared to take reasonable steps to provide meaningful access to individuals beyond those who walk into, or contact that entity.

Under the new rule, a “qualified interpreter” is defined as an interpreter who “via a remote interpreting service or an on-site appearance”:
1. adheres to generally accepted interpreter ethics principles, including client confidentiality;
2. has demonstrated proficiency in speaking and understanding both spoken English and at least one other spoken language; and
3. is able to interpret effectively, accurately, and impartially, both receptively and expressly, to and from such language(s) and English, using any necessary specialized vocabulary and phraseology.

By moving the legal standard from “competent” interpreters to “qualified” interpreters, DHHS is increasing the standard of care and legal duty owed to LEP and Deaf and Hard of Hearing patients and requiring organizations that receive federal funds to bear the financial burden of increasing the professionalism of their language access services.

The fact that an individual who has above average familiarity with speaking or understanding a language other than English does not suffice to make that individual a qualified interpreter for an individual with limited English proficiency.

The Agency for Healthcare Research and Quality has tools for providers to use to assess and improve health literacy efforts to help patients better understand their conditions.
Minors
In general, unless emancipated, minors do not have decision-making capacity and do not have the legal ability to provide informed consent. Consent for treatment of minors is provided by parents, guardians or proxies that have been appointed by parents or guardians. Since consent refers to agreeing to an intervention or activity on oneself, in theory, one cannot provide consent for another. For this reason, some informed consent documents for minors are titled “Permission Documents”.

There are state-specific exceptions for minors aged 12-18 seeking specific types of treatment related to sensitive issues such as reproductive, sexually transmitted disease, substance abuse and psychiatric counsel and treatment. If the patient is able to be seen independently, then the patient is also able to authorize release of medical records.

There are also state-specific requirements and recommendations for unaccompanied minors attending routine appointments.

Minors should be included in decision-making at a developmentally appropriate level and assent should be sought when possible. Assent is the agreement of someone who is not able to give their legal consent. If the minor does not assent and opposes the parental, guardian or proxy decision, ethics consultation or legal routes may be appropriate.

If a minor is involved in research or a trial study, the consent of their parent or guardian is required and the minor subject’s assent is required.

The primary responsibility for the provider is the well-being of the minor. Therefore, if the parental or guardian decision places the minor at risk of harm, ethics consultation or legal routes may be appropriate.

Emancipated Minors
Emancipation is a legal process through which a minor child obtains a court order that ends the rights and responsibilities that the minor’s parents owe to the child. Some states provide partial or complete emancipation.

Emancipated minors are considered to be adults for several purposes including the ability to enter into a contract and consent to medical care. Emancipation ends the parents’ rights to control the minor child or to participate in decision-making about the minor.

When obtaining informed consent from a minor who advises that they are emancipated, the provider should document the emancipated minor exception and document how the exception was determined. Determining emancipation without viewing a court order is challenging for providers and all information resulting from a provider’s evaluation should be documented. There are specific challenges related to three categories of minors:

- A minor who is married but does not have court ordered emancipation
• A minor who has a child but does not have court ordered emancipation
• An emancipated minor who has a child
  o An emancipated minor who has a child and signs an informed declination on behalf of the child is extremely challenging and may require child protective services involvement

States vary on what rights and responsibilities these minors have related to informed consent. When dealing with these specific individuals, providers should consult Risk Management to assist with your analysis.

There are also specific challenges related to a minor who is a “run-away.” Being a run-away does not make the child legally emancipated. If the child discloses that they are a run-away because of parental abuse, child protective services should be contacted.

**Dot Phrases (AKA Smart Phrases) and EHR copy & paste usage**

Dot phrases are intuitive abbreviations of the text included in the informed consent. Dot phrases can either currently exist in the EHR system or they can be created.

• The dot phrase should be named respectfully, accurately and clearly
• The provider should ensure that the record documentation reflects the actual performance of the informed consent conversation. Both the conversation and the documentation will have to align with the dot phrase text. The dot phrase can be used as a framework for the note, but the individual informed consent will need to edited and customized for each patient to demonstrate that it is patient-specific and visit-specific.
  o Metadata analysis will confirm or negate that this has been performed by the provider and therefore can hurt or support the provider’s position should this arise in a case.
  o This is especially evident if the dot phrase uses one gender.

Dot Phrases and copy and paste functions have parallel risks and benefits.
The benefits include:
• Ease
• Time efficiency

The risks include:
• Introduction of inaccurate information
• Text is not specific to the patient or the procedure

**Delegation (“But I do not have time to do all of this”)**

One of the biggest barriers to a comprehensive informed consent process is the provider’s assessment and declaration that they do not have enough time to engage in the informed consent process.

**Delegation is not an option.** A nurse educator or another health care provider may provide education, but the provider who is performing the treatment/intervention is responsible for the final conversation, confirming that the patient had full understanding of the education that was provided, securing the
patient’s agreement and consent and for documenting the same on the informed consent document and in the medical record.

The rationale in support of the provider’s duty to confirm that the patient had full comprehension of any education provided by another healthcare provider is based on the provider/patient relationship. The patient would not be in a relationship with the provider unless the patient trusted the provider. Therefore the provider has a duty to confirm the patient’s full comprehension of the risks, benefits, alternatives and common complications up to and including death and satisfy any questions.

**Informed consent for recurrent procedures**
When the treatment involves recurrent procedures, it is not always necessary to repeat the informed consent process. If there has been no significant deviation from the original plan, condition or diagnosis(es) that would change the initial intent of the consent, additional and repeat consent forms are not necessary.

If there have been no significant deviations from the original plan, condition or diagnosis(es), this should be documented in the medical record as the rationale to support and explain why a new consent was not obtained. In general, if there have been no changes, an informed consent can remain active for one year.

**Informed consent for multiple specialties in one procedure**
For procedures involving multiple specialties, each provider should have their own consent form and document the informed consent conversation in the medical record. The consent form should also include the sequencing of each provider’s performance in the procedure. The separate anesthesia informed consent should address the sequencing along with the perioperative management of preexisting comorbid conditions.

**Informed consent in telehealth and with wearable devices**
*Telemedicine*
There is no “one-excepted definition” for telemedicine. Every state has a definition and state regulations related to informed consent. The Center for Connected Health Policy maintains a website that provides information related to each states’ definitions, eligible providers, consent mandates and more. The American Telemedicine Association maintains a website that includes state guidelines and sample telemedicine forms.

In general, most state definitions will include the following elements:
- a health care practitioner uses HIPAA-compliant
  - electronic communications and information technology
  - interactive real-time audio and video telecommunications or store-and-forward technology
- to deliver covered services that are within his or her scope of practice
• to a patient at a different site

Informed consent in telehealth and with wearable devices extends to the risks that are specific to the routes and delivery of care. Reliance on technology combined with issues related to distance encounters results in exposures that should be disclosed to the patient.

Many states do not require a separate signed informed consent form for telehealth. Even if your state does not require a specific or separate form, it is best practice to follow the informed consent process which includes the patient signing the informed consent form.

Elements specific to informed consent with telehealth
  • Description of telehealth service to be performed and telehealth technologies, including disclosure of limitations. This description should be conveyed using plain language
  • Disclosure of risks specific to the electronic delivery of care and measures implemented to address each risk
    o Risks specific to electronic delivery of care: technology disruptions, transmission errors, failures, vulnerabilities to hacking of PHI
    o Defining a plan addressing disruptions and failures
    o Disclosure of security and privacy measures to address technology vulnerabilities
  • Names of involved health providers, provider credentials and qualifications
  • Defining patient responsibilities before, during and after the telemedicine encounter
  • Defining a plan for on-going or future care
  • Defining a plan for alternative care if needed in case of an emergency

*Wearable devices*

Wearable devices include hardware and software technology that enables real-time monitoring delivering patient-generated data that informs healthcare decision making.

The wearable device market is growing exponentially and state laws are not keeping up with this growth. Consequently, there are minimal regulations that address mandatory health care provider policies or actions.

Recommendation that if wearable devices are used to generate real-time data that informs healthcare decision making, that a specific informed consent be signed that contains the elements specific to informed consent with telehealth. Specific patient responsibilities should be defined which include responsibility for follow-up after a data point deviation has been transmitted and becomes known to the patient.

*Informed consent management*

*Bank of templates/automated system*
There are frequent questions about the value of them creating or purchasing a bank of general templates or investing in an automated system. There is value in templates that offer uniformity as this is a means to present the same information in the same way.

This is an operating decision that involves analysis of trade-offs:

- **Efficiency/uniformity and quality:** Creating a bank of templates or purchasing templates requires an initial investment in time and money.

  The template, however will not be useful in its native state and will require individualization to make it patient-centric and specific to the individual and the situation. If the template is not changed, the quality of the informed consent will suffer.

  General templates and automated systems will not be state-specific and therefore will require customization so that the consent complies with state regulations. Jurisdictions may have specific language, format or other requirements.

- **Efficiency and alignment with organization mission, vision and values:** All informed consent forms should align with the organization’s mission, vision and values (“MVV”). For example, if the MVV uses patient-centric language, customer-focused collaboration, addresses respect and empathy or similar sentiments, the general templates may be out of alignment with the MVV, which can be problematic.

Template banks should be reviewed and evaluated to determine if they are literacy appropriate. If the templates require edits to move them to plain language, a content review should be performed to assure that the intent and the consent specifics have not changed.

If the automated system contains pre and post educational material and instruction packets, efficiencies can be realized. However, the provider obtaining the consent remains responsible for determining patient comprehension.

**Informed refusal/Informed declination**

Informed refusal is not the opposite of informed consent. The opposite of informed consent is uninformed consent.

Informed consent is from the patient’s perspective. If informed consent was from the provider’s perspective, it would be labeled “informed compliance”.

Informed refusal is the healthcare industry phrase used to describe a patient’s refusal to follow the provider’s order or recommendation. Informed refusal is from a provider’s perspective and is therefore paternalistic and not patient-centric. Since informed refusal is from the provider’s perspective, it would align with informed compliance. No healthcare provider utilizes the label “informed compliance”.

Informed refusal is unconsciously or consciously accompanied with negative value judgments from the provider’s perspective, which in turn influences and impacts the patient.

Just as the medical lexicon is changing regarding describing patient non-compliance as “patient non-adherence”, the labeling of “informed refusal” can be changed to “informed declination”.

Using the label of “Informed Declination” aligns with patient autonomy, is patient centric and will likely align with organizations’ missions, visions and values, as these declarations are generally written with the patient as the focus and at the core of the mission, vision and values.

Patient non-compliance refers to a deliberate or intentional refusal by the patient to comply with the provider order or recommendation. Patient non-adherence implies that the patient is not able to follow the order or recommendation. Non-adherence opens the door to the reason why the patient is unable to follow recommendations. There are many individual, social, legal, environmental and economic explanations for non-adherence including:

- Financial issues
- Poor communication between provider and patient
- Patient mistrust of provider
- Inadequate education of condition and recommendation/procedure
- Unpleasant side effects of medication
- Family issues or turmoil

Recognition of social determinants of health¹ and health inequalities related to an individual patient or a patient population can enable a more productive and constructive dialogue between provider and patient that can result in legal and environmental resolutions that may be at the root of the non-adherence.

Broadening the perspective that the health care system is the key driver of health and health outcomes to recognizing that non-health related factors significantly influence the patient’s ability to adhere to a provider’s recommendation, can expand avenues that a provider can take with a patient. For example, a patient with recurrent asthmatic attacks may decline to consent to a diagnostic procedure or a treatment intervention if the patient knows that the asthmatic attacks occur because of indoor environmental triggers (mold, vermin). Unless the trigger is eradicated, the patient will have recurrent asthmatic attacks. In these cases, the provider can contact social services or the local Medical Legal Partnership². These resources would be able to determine whether there is a state law that compels

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¹ Social Determinants of Health are the conditions in which people are born, grow, live, work and age and relate factors such as socioeconomic status, education, neighborhood and physical environment, employment, social support networks, and access to health care to the ability to improve and sustain health and reduce health disparities.

² The medical-legal partnership (MLP) model integrates legal care and medical care to effectively and sustainably reduce chronic stressors and their associated negative health impact among low-income populations. In this model, medical and legal providers work together as a team to help low-income individuals get the legal assistance.
landlords to eradicate mold, vermin or other asthma triggers and would assist the patient in the proper notice and procedure to compel or they may provide legal representation to sue a landlord.

Informed declination can be used to describe the patient’s perspective. Changing the label from informed refusal to informed declination, moves the informed decision from a dualistic exercise of either complying or refusing, which eliminates patient autonomy because the label implies “disobedience” to an exercise where a patient has autonomy.

<table>
<thead>
<tr>
<th>Label Implications</th>
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</thead>
<tbody>
<tr>
<td><strong>Non-Compliance/Informed Refusal</strong></td>
</tr>
<tr>
<td>Paternalistic</td>
</tr>
<tr>
<td>“Closes the door”</td>
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<tr>
<td>Patient submission: Patient is caused to make a decision by the provider’s order/recommendation</td>
</tr>
<tr>
<td>Use of these terms accompanied by negative value judgments</td>
</tr>
<tr>
<td>Categorical imperative: “Do X because it is right”</td>
</tr>
<tr>
<td>This perspective enables the provider to have a conversation with the patient about their reasons for not adhering to recommendations or their decision to decline a procedure. The patient may have psychosocial and economic reasons that interfere with their ability to adhere to a plan or recommendations</td>
</tr>
<tr>
<td>Some forms use the language: “In spite of this understanding, I refuse to consent to the treatment”: This language is drafted from the provider perspective and conveys a paternalistic context</td>
</tr>
<tr>
<td>Use of this language prioritizes the provider’s opinion and recommendation over the patient’s reasoning which could include values and trade-offs.</td>
</tr>
<tr>
<td>Recommend not using language such as “In spite of ...”.</td>
</tr>
<tr>
<td>Instead, draft a declarative statement, “I decline to consent to the treatment”</td>
</tr>
</tbody>
</table>

they need for a wide range of social stressors. These teams have the ability to transform practices, policies, and systems. Attorneys advocate on behalf of patients to help them address legal concerns ranging from housing, to health insurance to immigration. Having these legal concerns met can dramatically reduce chronic stress and improve health outcomes in low-income populations. (From: Medical-Legal Partnerships as a Strategy to Improve Social Causes of Stress and Disease)
**Tools**
Recommendation for two tools in addition to clear and comprehensive documentation of the patient declination.

Tools are designed to provide the patient with the information on possible consequences of declining treatments, procedures or recommendations/plans. When the informed declination is explained to the patient and the patient is asked to sign the form, the patient often reconsiders and may decide to consent.

Additionally, a non-adherent patient or a patient who declines treatment, procedures or recommendations may subsequently develop an illness or disease or their condition may worsen and the patient may sue the provider for a missed or delayed diagnosis. Using the two tools below along with clear and comprehensive documentation of the patient declination will provide defense support.

**Documentation recommendations:**
- If the patient is non-adherent or declines recommended care, discuss and document the patient’s reasoning. Explore alternatives and document the patient response.
- If the patient states that their declination is due to a lack of understanding, incorporate audiovisuals or multimedia and document.
- Documentation of the declination should include:
  - The patient has declined the recommended care
  - The patient’s reasons for declination
  - The consequences of declination have been explained in plain language and that the patient understood the risks of the declination
  - The patient’s signature was obtained on the informed declination form
  - If the patient is uncooperative, the signature of a witness should be obtained and documented in the medical record
Informed Declination Letter To Patient From Provider

Date

Dear (Patient Name),

On (date), we discussed _________________________ and I, as your provider, recommended ___________________________. We discussed the benefits, risks, and alternatives and you signed an Informed Declination Form.

I have reviewed your medical record and I again recommend ___________________________. If you choose to not follow the recommended plan of care, you could experience the following risks, (up to and including death).

You and I are team members in managing your health and if you have any questions related to your condition, my recommendation or the consequences of your declination, please call our office to schedule an appointment.

Sincerely,
Informed Declination

This signed document is my formal statement acknowledging that I ______, a patient of/ at ______ am making an informed decision to decline the recommended advice of my provider.

My provider ____________________ has recommended the following treatment/procedure/plan:

The risks and benefits of the recommended advice of my provider have been explained to me. We have discussed alternatives. I have had an opportunity to discuss the risks and benefits and understand the risks and benefits that were recommended by my provider.

We have discussed the potential benefits and they include:

We have discussed the potential risks up to and including death and they include:

____ Death
____ Permanent disability/disfigurement
____ Additional pain and/or suffering
____ Risks to unborn fetus
____ Other risks:

We have discussed the following alternatives with their potential benefits and risks and they include:

My signature acknowledges that:
1. My medical condition has been evaluated and explained to me by my provider who has recommended the above treatment/procedure/plan. We have discussed my condition and I understand my condition.

2. My provider has explained and we have discussed and I understand the potential benefits and risk of the recommended treatment/procedure/plan and alternatives.
3. My provider has explained and we have discussed and I understand the potential risks with not following through with the recommended treatment/procedure/plan.

4. I have had an opportunity to discuss all questions related to the recommended treatment.

The patient or representative has read this form or had it read to him or her.

_____ The patient or representative states that he or she understands the information in this form.

_____ The patient or representative has no further questions

_____ I am declining to consent to the recommended treatment.

__________________________________
PATIENT OR REPRESENTATIVE PRINT

__________________________________
PATIENT OR REPRESENTATIVE SIGNATURE

__________________________________
PROVIDER SIGNATURE

__________________________________
WITNESS PRINT

__________________________________
WITNESS SIGNATURE

WITNESS CONTACT INFORMATION:

__________________________________
ADDRESS

__________________________________
PHONE