



## Informed Consent for Anesthesia Care

### *Policy and Practice Considerations*

The following considerations are solely for informational purposes, are not intended to provide legal advice, and should not be considered or relied upon as legal guidance. Federal, state, local, and accreditation requirements vary and are subject to change. Please seek all necessary legal and expert assistance regarding the requirements specific to your practice.

Table of Contents	
<b>Purpose</b>	<b>1</b>
<b>Introduction and History</b>	<b>2</b>
<b>Anesthesia Informed Consent Process: Background and Considerations</b>	<b>2</b>
<b>Consideration - Separation of Anesthesia Informed Consent Process from Surgical/Procedural Informed Consent Process</b>	<b>2</b>
<b>Elements of Anesthesia Informed Consent Process</b>	<b>3</b>
<b>Timing of Anesthesia Informed Consent Process</b>	<b>6</b>
<b>Emergencies</b>	<b>6</b>
<b>Withholding Information</b>	<b>7</b>
<b>Informed Consent Policy Considerations</b>	<b>7</b>
<b>Informed Consent Practice Considerations</b>	<b>7</b>
<b>Patient Communication and Health Literacy</b>	<b>7</b>
<b>Informed Consent Form</b>	<b>8</b>
<b>Patients Requiring Special Assistance</b>	<b>9</b>
<b>Special Additional Considerations: Informed Consent for Obstetric Patients</b>	<b>11</b>
<b>Prenatal Education, Communication, and Timing of Informed Consent</b>	<b>11</b>
<b>Anesthesia Consultation with At-Risk Parturients</b>	<b>12</b>
<b>Pregnancy in Minors</b>	<b>12</b>
<b>Maternal-Fetal Conflict</b>	<b>12</b>
<b>Conclusion</b>	<b>12</b>
<b>Appendix: Additional Resources - Patient Communication, Health Literacy, and Cultural Competency</b>	<b>13</b>
<b>References</b>	<b>15</b>

### **Purpose**

This document summarizes the ethical and legal concepts of informed consent for anesthesia, describes the elements of informed consent, and provides recommendations for engaging in the informed consent process for anesthesia services. It serves as a resource document for anesthesia professionals, healthcare professionals, and healthcare facilities for development of anesthesia informed consent policy and practice considerations. Anesthesia professionals, including Certified Registered Nurse Anesthetists (CRNAs), are responsible for following the informed consent requirements specified in federal, state, and local law, accreditation standards, and facility policies.

The American Association of Nurse Anesthetist (AANA) [\*Standards for Nurse Anesthesia Practice\*](#)<sup>1</sup> require that CRNAs “[o]btain and document informed consent for the planned anesthetic intervention from the patient or legal guardian, or verify that informed consent has been obtained and documented by a qualified professional.” CRNAs also have an ethical duty to obtain informed consent under the AANA

*Code of Ethics for the Certified Registered Nurse Anesthetist*:<sup>2</sup> “The CRNA verifies that a valid anesthesia informed consent has been obtained from the patient or legal guardian as required by federal or state laws or institutional policy prior to rendering a service.”

CRNAs engage in the anesthesia care informed consent process and obtain informed consent from the patient when the patient undergoes surgery or an invasive procedure that requires anesthesia services or when the CRNA provides pain management services. CRNAs may also obtain informed consent for other procedures, such as the administration of blood and blood products and the insertion of central lines, in accordance with facility policy.

### **Introduction and History**

Informed consent is grounded in an ethical and legal concept—that patients have the *right* to understand what is being done to their bodies (personal autonomy) and agree to the potential consequences of the healthcare intervention (self-determination and self-decision).<sup>3</sup> The legal requirement of informed consent arose from two separate theories of liability articulated in court decisions. The first is common law battery, which is the performance of a procedure (unauthorized touching) without valid consent, even though it may have been performed without negligence. Justice Cardozo, in the 1914 landmark case of *Scholendorff v. Society of New York Hospitals*, asserted the principle of the patient’s right of self-determination.<sup>4</sup> The second is negligent failure to warn and arises where the healthcare professional fails to warn the patient of risks or to instruct him/her of alternative methods of treatment that are available.

Failure to obtain informed consent compromises patient autonomy, may increase patient safety risk due to incomplete patient-clinician communication, may constitute negligence, battery, breach of contract, or other legal claims, and may lead to professional discipline.<sup>5,6</sup> A robust patient-centered informed consent process is a model of shared decision-making that enhances patient safety, improves patient satisfaction, meets ethical and legal duty to the patient, increases staff morale, reduces legal risk to the healthcare provider and organization, and helps ensure compliance with regulatory and accreditation requirements.<sup>7</sup>

### **Anesthesia Informed Consent Process: Background and Considerations**

Informed consent is much more than a signed form; the anesthesia professional and the patient develop the anesthesia plan through discussion of alternatives and risks and benefits of the plan.<sup>8,9</sup> The informed consent process provides the opportunity for the patient to be an active participant in anesthesia care decision-making and to clarify any questions he or she may have.<sup>10-13</sup> Engaging in a patient-centered discussion allows the anesthesia professional and patient to develop the anesthesia care plan by sharing information and evidence; exploring patient needs, preferences, and fears; and identifying recommendations and choices.<sup>14-17</sup> The informed consent process may occur in one discussion or during several discussions.<sup>7</sup> If desired by the patient, the family or caregiver may participate in this process. If the patient is incapacitated, the legal decision maker participates in this process. The legal decision maker is the person named in an advance directive under durable power of medical attorney or allowed under state law to make healthcare decisions for a person who is no longer able to make decisions on his or her own. Other terms for “legal decision maker” are healthcare agent, healthcare proxy, legally authorized representative, or surrogate decision-maker. Informed consent, regardless of whether it is provided by the patient or the patient’s legal decision maker, is documented in the healthcare record.<sup>18</sup>

### ***Consideration - Separation of Anesthesia Informed Consent Process from Surgical/Procedural Informed Consent Process***

The AANA recommends separating the anesthesia informed consent process and anesthesia informed consent form/documentation from the surgical/procedural informed consent process and form.

Combining the informed consent for anesthesia with the procedural or surgical consent deemphasizes anesthesia’s role and may increase exposure to lawsuits.<sup>19</sup> The anesthesia professional is most qualified to discuss with the patient the risks and benefits for each type of anesthesia/pain management modality,

perioperative management of preexisting comorbid conditions, and patient preferences.<sup>19,20</sup> It is possible that a patient who has the capacity to provide informed consent for the surgery/procedure may not have the capacity to provide informed consent for anesthesia.<sup>19</sup>

Separate and appropriate documentation of the anesthesia informed consent process is also important evidence that an effective informed consent process occurred.<sup>21</sup> When the anesthesia informed consent process is implemented separately from the surgical/procedural informed consent process, consider including on the anesthesia informed consent form a patient acknowledgment that the surgical/procedural consent process occurred and that he/she understands the reason for the anesthesia.

The AANA previously collaborated with a risk management consultant to develop [model anesthesia consent forms](#) that are not copyrighted and may be adapted for use. These forms are not presented in an “as is” state and should not be utilized as such. Modifying these forms for your practice requires thoroughly investigating your state informed consent laws and/or consultation with legal counsel. Development of informed consent forms must also follow applicable facility processes and policies. *The AANA does not warrant these forms as being free of legal defects, and providers who elect to use them as the foundation of their policies elect to do so at their own risk.*

### ***Elements of Anesthesia Informed Consent Process***<sup>13,15,16,22-24</sup>

- **Competence and decision-making capacity:** The patient has the legal authority to consent (competence) and the ability to decide to receive specific anesthesia care (capacity).  
**Disclosure of information:** The patient is adequately informed of relevant information, including at a minimum:
  - Nature and purpose of the proposed anesthesia technique(s)
  - Risks, benefits, side effects of anesthesia technique(s)
  - Alternatives and their risks, benefits, and side effects
  - Risks of not receiving the anesthesia care
- **Understanding of disclosed information:** The patient demonstrates understanding of the information disclosed and presented by the anesthesia professional.
- **Voluntary consent:** The patient voluntarily consents to the planned anesthesia care in the absence of coercion or duress.
- **Documentation:** The healthcare record contains appropriate documentation evidencing the patient’s informed consent for anesthesia.

### ***Competence and Decision-making Capacity***

#### *Competence*

“Competence” refers to the patient’s legal authority to make healthcare decisions. Most states consider a patient to be competent, unless otherwise determined by a court, if they are 18 years or older.<sup>25</sup>

#### *Minors*<sup>23</sup>

Generally, parents or legal guardians are legally competent to consent to the healthcare of minors unless state law provides an exception for special circumstances. Depending on state law, these exceptions may allow minors to consent to care, or certain types of care, if minors are:<sup>25-29</sup>

- Emancipated by court order
- Married
- Engaged in active military service
- Living independently from their parents (e.g., self-sufficient, homeless)
- Pregnant

- Parents
- High school graduates
- Seeking specific types of healthcare treatment (e.g., pregnancy-related services, mental health treatment, drug and alcohol abuse treatment)

In the event the minor patient has an emancipated status (e.g., court order, department of motor vehicles identification card that is issued to an emancipated minor, marriage certificate, military identification card, birth certificate and minor's written affirmation of meeting the state law's criteria for living independently) the anesthesia professional should inquire as to whether the appropriate review and verification has taken place by the facility and document the result of the inquiry in the healthcare record.<sup>25,30</sup>

Some states have adopted the "mature minor doctrine," which enables a court (or the healthcare provider depending on state law) to determine that a minor is sufficiently "mature" to refuse consent or give legal consent in specific situations. Under this exception to general consent rules, the extent of the risk in the decision and the age and maturity of the minor are key determinants.<sup>31-34</sup> If a court determines this status, a copy of the court order should be placed in the healthcare record.

Even if the minor does not have the legal authority to consent, he or she should be included in the informed consent discussion if developmentally appropriate, and his or her cooperation and agreement ("assent") should be sought.<sup>35</sup>

Refer to facility policy and consider consultation with facility legal counsel or ethics committee in situations involving emancipated or mature minors, minors who refuse to assent to the anesthesia care, or parental refusal of anesthesia care that is in the minor's best interests.

#### *Decision-making capacity*

"Decision-making capacity" should not be confused with "competence," or legal authority to provide informed consent. "Decision-making capacity" refers to the patient's ability to make a meaningful decision at a specific time about whether or not to undergo anesthesia, including appreciating the significance of the anesthesia plan of care and its potential consequences. The anesthesia professional evaluates the patient and determines capacity to make the specific healthcare decision.<sup>21</sup>

If the patient has received anxiolysis or analgesia, the anesthesia professional determines whether the patient has decision-making capacity by considering the medication's effects and the patient's demonstration of rational reasoning and understanding. If a patient's decision-making capacity raises concern, the anesthesia professional may consider having a structured assessment implemented (e.g., the Mini-Mental State Examination (MMSE)) or seeking a psychiatric, ethics, or legal consult.<sup>7,19,36-38</sup> Once a determination has been made, it is important to document the determination of the patient's decision-making capacity, the objective facts supporting the decision, and the consultation or opinion obtained in the healthcare record.<sup>39</sup>

Patients who are or become incapacitated do not lose their right of informed consent; instead, decision-making authority is transferred to a legal decision maker to make decisions on their behalf.<sup>13,40</sup> State law governs who is considered a legal decision maker and often indicates the priority order in which family members may be contacted if the patient lacks decision-making capacity.<sup>21,36</sup> A patient can delegate his or her right to make informed decisions to another person in accordance with state law.<sup>13</sup> This designation continues throughout the patient's anesthesia

care, unless expressly withdrawn, either orally or in writing, by the patient.<sup>41</sup> For additional discussion, please see [American Association of Nurse Anesthetists Reconsideration of Advance Directives - Practice Guidelines and Considerations for Policy Development](#).

### ***Disclosure of Information***

The anesthesia professional provides the patient with information that is relevant and helpful to making a meaningful, informed decision about the anesthesia care.<sup>15</sup> Informed consent begins with an explanation of the patient's decision-making role and continues as an interactive process of communication about alternatives, risks and benefits during which the patient is encouraged to ask questions related to anesthesia care that are addressed by the anesthesia professional.<sup>7</sup> Information, if applicable to the anesthesia care, about goals for care, possible recovery concerns, and the post-anesthesia period are also discussed.<sup>15,23,34</sup>

The degree of disclosure regarding risks and benefits of anesthesia varies by state and local law. Many jurisdictions use a "reasonable person" standard, or what is material to a reasonable person's decision.<sup>10</sup> Risks that should be disclosed are reasonably foreseeable, but it does not have to include every possible risk. "Material" (i.e., significant) risks are those that a reasonable person would want to be made aware of when making decisions about an anesthetic procedure. They include risks that commonly occur as well as those risks that are rare, but may result in severe morbidity and mortality.<sup>21,30</sup> Some jurisdictions use the "professional practice" standard, or what a reasonable practitioner would disclose to a patient under similar circumstances.<sup>30</sup>

### ***Special Consideration: Disclosure for Unplanned Conversion to General Anesthesia***

The anesthesia professional discusses with the patient the need for possible conversion to general anesthesia in the event of inadequate sedation or regional anesthesia. The discussion of possible modifications in the plan for anesthesia allows the patient the opportunity to discuss any concerns he or she may have related to general anesthesia.<sup>42,43</sup>

### ***Understanding Disclosed Information***

The patient must demonstrate an understanding of the plan for anesthesia care in order to make an informed decision and to decide whether to receive anesthesia care.<sup>5,12,44</sup> Variables such as language, cultural and religious beliefs, health literacy, and health impairments may impact a patient's understanding of the procedure.<sup>9,45,46</sup> Please see *Informed Consent Practice Considerations* below.

### ***Voluntary Consent***

Upon completing the informed consent discussion, the patient exercises the right to make informed decisions about anesthesia care. "Voluntariness" indicates that the patient's consent is free and voluntary without any external influences like coercion, persuasion, or manipulation.<sup>47,48</sup> Exaggerating the harm of not consenting to the recommended care or the benefits of accepting the recommended care may also be considered coercion.<sup>13,34,48</sup> The patient has the right to withhold consent, revoke consent, or provide consent after initially withholding consent.<sup>34,35</sup>

### ***Documentation***

Following the interactive development of the anesthesia plan and informed consent discussion, the patient or legal decision maker consents to the anesthesia and signs the anesthesia informed consent document indicating date and time and relationship, if applicable, in accordance with federal, state, and local law, accreditation or other requirements, and facility policy.<sup>49</sup> The informed consent form should not be signed until the patient's questions have been answered to his or her satisfaction.<sup>50</sup> The Centers for Medicare & Medicaid Services (CMS) Hospital Conditions of Participation (CoPs) state that the healthcare record must contain "[p]roperly

executed informed consent forms for procedures and treatments specified by the medical staff, or by federal or state law if applicable, to require written patient consent.” The current companion CMS hospital interpretive guideline (November 20, 2015) states, “The medical record must contain a document recording the patient’s informed consent for those procedures and treatments that have been specified as requiring informed consent....The informed consent form contained in the medical record should provide evidence that it was properly executed.”<sup>51,52</sup> CMS also addresses requirements for informed consent for critical access hospitals (CAHs) in the CAH CoPs and ambulatory surgical centers (ASCs) in the ASC Conditions for Coverage.<sup>53,54</sup>

Federal, state and local law, as well as accreditation standards, may also specify additional requirements, such as the necessity for practitioner, witness, and if applicable, interpreter signatures. Regardless of whether these signatures are required, they may be helpful if the informed consent process or documentation is challenged.<sup>55</sup> Witness signatures verify that the witness saw the patient/patient’s legal decision maker sign the document. Identify an appropriate available witness. All signatures should have the date and time noted.<sup>22,23,51</sup>

In addition, the anesthesia professional may include in the patient’s healthcare record a note stating that he or she met with the patient and/or legal decision maker, and informed consent was obtained. This note may include the time, date, and name of persons present.<sup>10,23,58</sup> If significant changes to the agreed anesthesia plan occur after the patient is sedated or anesthetized, the reasons for the change should be documented in the anesthesia record.<sup>52,59</sup>

Formal documentation of informed consent provides evidence that the informed consent process has been completed, substantiates billing, and may help protect anesthesia professionals from legal liability or disciplinary action in case the patient subsequently challenges the proposed care.<sup>16,59</sup>

### ***Timing of Anesthesia Informed Consent Process***

Some facility policies will allow for informed consent to be obtained within a specified time period prior to the procedure. Regardless of policy or other requirements, the process and forms should be based on the patient’s current health status. If the patient’s condition changes after the process has been completed, then the risks, benefits, and alternatives may also have changed. The anesthesia professional and patient should engage in the informed consent process again, including signing the document that completes the process.<sup>60</sup>

### ***Emergencies***

Emergencies are exceptions to completing the informed consent process. **Emergencies and Implied Consent:** Immediate treatment or intervention is warranted because the patient is unconscious or incapable of consenting and the harm from failing to perform the procedure is imminent and outweighs the potential harm from performing the procedure.<sup>61</sup> Generally, if a true emergency exists, consent is not required since it is implied. Emergencies should be documented in the patient’s record.

When patient status permits, the healthcare professional should attempt to secure the consent of the legal decision maker, or if there is no legal decision maker, close family members.<sup>13,37,61</sup> Generally, legal decision makers provide a “substituted judgment,” or decision based on knowledge of what the patient would have wanted. When the patient’s wishes are unknown, the legal decision maker decides according to the “best interests” of the patient. An advance directive executed by the patient may identify the legal decision maker or specify the patient’s wishes.<sup>13,18,62</sup>

### ***Withholding Information***

Anesthesia professionals must offer all patients the opportunity to receive relevant healthcare information. Some patients may limit the scope of the information they wish to receive and their preferred methods for receiving this information, or waive their right to receive this information. They may want certain information to be withheld, to involve family members or caregivers in the decision-making process, or to appoint a family member or caregiver as a proxy. Anesthesia professionals, within the limits of applicable legal requirements, should respect their patients' voluntary choices about receiving healthcare information after educating them about the informed consent process and shared decision-making.<sup>34,38,62-65</sup> A note should be placed in the patient's healthcare record describing the patient's wishes, outlining the relevant facts and circumstances, and summarizing the information provided to the patient and/or family member/caregiver.

### **Informed Consent Policy Considerations**

A facility's informed consent policy should reflect applicable federal (e.g., CMS CoPs<sup>51,53,54</sup>), state, local and accreditation requirements, reinforce a culture that values truly informed consent, and undergo legal review.

Topics for policy consideration include:<sup>8,15,55,66-70</sup>

- Anesthesia informed consent process and documentation
- Persons authorized to conduct the consent process
- Criteria for legal decision maker to provide informed consent
- Emergencies and informed consent
- Use of qualified healthcare interpreters
- Expiration of informed consent
- Informed consent form elements
- Related educational materials
- Processes for obtaining clarification in special circumstances (e.g., contacting risk management or other applicable department/committees)
- Quality reporting and improvement program

### **Informed Consent Practice Considerations**

#### ***Patient Communication and Health Literacy***

Health literacy is defined as the ability to obtain, process, and understand basic health information and services needed to make appropriate health decisions.<sup>71</sup> Limited health literacy disproportionately affects vulnerable populations, including older adults, minorities, and persons with limited education.<sup>72,73</sup> Limited health literacy is associated with less comprehension of informed consent and lower informed consent recall.<sup>7</sup> Because identifying individuals with low health literacy is not always possible, the anesthesia professional should provide information during the informed consent process that is clear and meaningful by validating patient understanding and tailoring the discussion to the patient.<sup>69,70</sup> Refer to Appendix A for additional resources on Patient Communication, Health Literacy, and Cultural Competency.

#### ***Considerations***

General considerations to facilitate clear communication with the patient during the informed consent process include:<sup>7,9,16,34,55,66,67,72,74-77</sup>

- Patient Engagement
  - Greet patients warmly/create a comfortable environment
  - Discuss informed consent in a quiet, private setting

- Engage language assistance services, such as qualified healthcare interpretation or translation services, if necessary
- Consider patient and family cultural values and health beliefs (e.g., socioeconomic status, family structure, health-seeking behaviors, immigration status, country of origin, migration history, and decision-making styles (e.g., familial, individual, delegated, deferential)
- Discuss the patient’s role during the informed consent decision-making process
- Modify the tone and pace of the discussion to provide information in a manner that meets the patient’s ability to process
- Be specific and concrete
- Use clear, simple language
- Communicate statistical information in a clear, concise, and accurate manner that is understood by the patient
- Draw simple pictures, use illustrations, or demonstrate with 3-D models
- Consider providing information or fact sheets that can be taken home before the anesthesia
  - Take the time necessary to obtain informed consent
    - Preadmission
      - Preanesthesia clinic visit for high-risk patients and as requested by the patient
      - Communicate by phone the day before the procedure
      - Use patient portal, if available
- Comprehension – assess the patient’s understanding of the information provided
  - Assess patient comprehension of information provided periodically during the discussion of anesthesia care
  - Repeat information in various formats at different times to encourage questions, improve comprehension and recall
  - Invite questions (e.g., “We discussed a lot of information. What questions do you have? What can we review again?”)
  - Answer questions
  - Repeat explanation, if necessary
- Consent Document and Process Completion
  - Allow patients ample time to read consent and consider options
  - Obtain verbal affirmation of consent
  - Emphasize that the patient should not sign the document if he or she does not understand any part of it
  - Obtain required signatures (e.g., patient/legal decision maker, anesthesia professional, witnesses, translator or interpreter)
  - Provide a copy of the executed written informed consent to the patient
  - If the informed consent process is completed prior to the immediate preanesthesia assessment and evaluation, verify patient agreement with previously provided informed consent and answer any concerns.

### ***Informed Consent Form***

General considerations for readability and clear communication within the anesthesia informed consent form include:<sup>22,67,78,79</sup>

- Use clear, consistent headings and large fonts (at least 12 point type size and common font (e.g., Times New Roman)
- Include white space
- Use an active, conversational tone



- Use simple sentences, short paragraphs, and plain, non-technical language where possible
- Avoid acronyms and abbreviations
- Provide clear definitions of any technical terms, abbreviations
- Consistently use the same words rather than synonyms
- Shorten form length by removing unnecessary material
- Validate the revised form with patients prior to implementation (e.g., surveys, questionnaires, individual interviews, group interviews)

### ***Patients Requiring Special Assistance***

Some patients may require special assistance. These patients may include those with limited English proficiency (LEP), visual or hearing impairments, learning disabilities, or cognitive impairments.<sup>45,80</sup> Federal, state, and local statutes, regulations, case law, and guidelines address communication with the patient to obtain informed consent. This includes Section 1557 of the Patient Protection and Affordable Care Act (ACA), known as the Nondiscrimination Provision, which prohibits an individual from being excluded from participation in, denied the benefits of, or otherwise subjected to discrimination on the basis of race, color, national origin, sex, age or disability in health programs and activities, any part of which is receiving Federal financial assistance. This law also extends to healthcare programs administered by an Executive Agency (e.g., CMS, Indian Health Service).<sup>81</sup> Under this law, healthcare facilities must take appropriate steps to provide communication with individuals with disabilities that are as effective as communications with others.<sup>82</sup> CRNAs should be aware of applicable laws and requirements that apply to patients with special needs and the informed consent process.<sup>81,83</sup> Considerations for engaging in the informed consent process with special needs patients include:

### ***Patients with Limited English Proficiency***

The regulation at 45 CFR Part 92 that implements Section 1557 (“ACA Nondiscrimination Final Rule”) requires covered entities receiving federal funding to take reasonable steps to provide meaningful access to services for individuals with limited English proficiency (LEP) eligible to be served or likely to be encountered in its health programs and activities, including providing free, accurate and timely language assistance services, such as qualified interpreters and translators. Nothing in this regulation requires individuals with LEP to accept language assistance services.<sup>82</sup>

LEP refers to individuals who do not speak English as their primary language and who have a limited ability to read, speak, write or understand English.<sup>83</sup> Approximately 57 million people or 20 percent of the U.S. population speak a language other than English at home.<sup>83</sup> Compared to the English-proficient population, the LEP population tends to be less educated, more likely to live in poverty, and experience significant barriers to health information and health services.<sup>83</sup> Failure to provide language services can lead to lack of informed consent, medical errors, increased liability risks, and regulatory and accreditation violations.<sup>55,66,83-85</sup>

Considerations for limited English proficiency include:<sup>15,45,66,80,83,86</sup>

- Inquire if a patient needs language assistance
  - Ask all new patients about their language preference and if they would like an interpreter
  - For patients who speak little or no English, use “I Speak” cards to identify the language they speak
  - Inform patients of the availability of language assistance services clearly and in their preferred language, verbally and in writing
- Use accessible and competent language assistance services, including the following as mandated for covered entities under the ACA Nondiscrimination Final Rule:
  - Qualified bilingual or multilingual staff who is designated by the covered entity to provide oral language assistance as part of the individual’s current job responsibilities

and who has demonstrated proficiency in speaking and understanding both spoken English and at least one other spoken language, including any necessary specialized vocabulary, terminology and phraseology, and demonstrated that he or she can effectively, accurately, and impartially communicate all healthcare information to the patient in his/her primary language

- Contracted qualified in-person, telephonic or video healthcare interpreter services
- Refer to the [ACA Nondiscrimination Final Rule](#) and [Summary of the Final Rule](#) for specific requirements
- Restrict the following language services:
  - Adult family members or friends unless emergency circumstances make this necessary, or the individual specifically requests that the accompanying adult interpret or facilitate communication, the accompanying adult agrees, and reliance on that adult for assistance is appropriate under the circumstances; this should be documented in the patient's record
  - Minors unless emergency circumstances make this necessary; this should be documented in the patient's record
  - Refer to the [ACA Nondiscrimination Final Rule](#) and [Summary of the Final Rule](#) for specific requirements
- Plan for interpreter services in advance (e.g., consider scheduling appointments on specific days or times when appropriate interpreter services are available)
- Provide written translation, performed by a qualified translator, of written content in paper or electronic form when necessary to provide meaningful access to individuals with LEP; refer to the [ACA Nondiscrimination Final Rule](#) and [Summary of the Final Rule](#) for specific requirements
- Use visual images, animation, and multimedia to increase knowledge
- Include the interpreter's name and signature with date and time on the informed consent form

#### *Patients with Cognitive Impairment*

Not all patients with cognitive impairment lack informed consent capacity.<sup>7</sup> A structured assessment (e.g., the Mini-Mental State Examination (MMSE) to assess cognitive impairment among older adults) may be necessary to evaluate the patient's capacity to consent.<sup>36</sup> If the patient lacks capacity to consent (e.g., a patient with advanced dementia), a legal decision maker must be designated.<sup>40</sup>

#### *Patients with Hearing Impairment*

Considerations for older adult patients and hearing-impaired patients include:<sup>87</sup>

- Patient - Wear personal hearing aids, use amplification device
- Anesthesia Professional
  - Speak slowly and clearly, with mouth uncovered and visible to the patient
  - Encourage the patient to interrupt whenever he/she needs clarification
  - Limit ambient and background noise – take the patient to a private room and close the door
  - Communicate the intended message with your body language
  - Verify that the patient understands the information
- Use a qualified interpreter if the patient prefers to communicate with sign language (refer to the [ACA Nondiscrimination Rule Final Rule](#) and [Summary of the Final Rule](#) for specific requirements)

#### *Patients with Visual Impairment*

Considerations for informed consent materials for visually impaired patients include:<sup>78,86</sup>

- Patient - Wear glasses, use magnifying device
- Anesthesia Professional
  - Present materials (e.g., informed consent form) orally

- Have translated into Braille
- Large font (at least 14-point), wide margins
- Avoid ALL CAPs or *italics*

## **Special Additional Considerations: Informed Consent for Obstetric Patients**

### ***Prenatal Education, Communication, and Timing of Informed Consent***

#### *Prenatal education*

An optimal time to inform and educate women about labor analgesia and anesthesia is during the prenatal period.<sup>12,88,89</sup> Comprehensive prenatal education programs educate women regarding possible analgesia and anesthesia care during labor.<sup>89</sup> Involving anesthesia professionals in prenatal education provides patients with reliable information regarding labor analgesia, anesthesia care if necessary for vaginal and caesarean delivery, and management of potential unexpected complications or emergency situations (e.g., vacuum extraction, emergency cesarean section).<sup>90,91</sup> Prenatal education programs set realistic expectations of the birth process, which may lead to positive experiences of labor.<sup>92,93</sup>

#### *Communication and Risk Disclosure to the Obstetric Patient*

The anesthesia professional supports the patient to make an informed decision by assessing the patient's knowledge and preferences in order to present accurate, adequate, and relevant labor pain management options (e.g., spinal, epidural, combined spinal-epidural, general anesthesia).<sup>94</sup>

Providing written (e.g., pamphlets, handouts) or electronic educational materials (e.g., websites) to patients is important.<sup>95</sup> These materials, however, should not substitute for discussion between the patient and the obstetrician and anesthesia professionals about the patient's plan of care.<sup>35</sup> These discussions allow the patient's healthcare professionals to address the patient's concerns, answer questions, and understand the patient's expectations and preferences.<sup>96</sup> Optimally, the obstetric patient and the healthcare professionals discuss the patient's plan of care before labor.

Obstetric patients should be informed that laboring analgesia is traditionally administered when indicated by the patient's progress of labor and following consultation with the obstetrician. However, the administration of laboring analgesia could be delayed secondary to an emergency that will make it impossible for the anesthesia professional to provide this service. Discuss with the patient that in such an emergency, alternative analgesia can be provided by the obstetrician if another anesthesia professional is unavailable to administer an anesthesia analgesic intervention.

Obstetric patients who have consented to regional anesthesia should be made aware of the potential for conversion to general anesthesia (e.g., a spinal wearing off, a high block) to facilitate delivery and help manage complications associated with severe adverse effects of neuraxial anesthesia and analgesia.<sup>35,97</sup>

Specific risks that should be disclosed include those with high incidence, high morbidity, or adverse fetal effects.<sup>35</sup> For example, potential complications of epidurals can range from post-dural puncture headaches to rare but significant nerve damage, and risks to the fetus.

#### *Timing of Informed Consent*

Optimally, the anesthesia professional should discuss anesthesia options before the patient goes into labor, or before the patient experiences severe pain and distress during labor.<sup>12,30</sup> However, informed consent is often obtained from the patient during active labor.<sup>88</sup> Evidence suggests that the majority of women are competent to give informed consent during the active phase of labor and can accurately recall the potential complications discussed despite pain and premedication.<sup>12,77,88</sup> If the informed consent discussion takes place during active labor, attempt to hold this discussion between contractions. The patient's support person should also be given the option to be present (with the patient's consent) during

this discussion.<sup>92</sup> Ask the patient and the patient's support person if they have any questions prior to completion of the informed consent process.

### ***Anesthesia Consultation with At-Risk Parturients***

A prenatal anesthesia consultation may be indicated when pregnancy is complicated by conditions such as morbid obesity, previous spinal surgery, adverse anesthesia experience, cardiac disease, or anticipated maternal or fetal risk. This consultation is needed to obtain maternal health and anesthesia history and to evaluate the patient to develop the plan for anesthesia care. During informed consent, the anesthesia professional will discuss the anesthesia risks. This consultation provides the patient with a plan for a safe labor and delivery.<sup>90,98</sup>

### ***Pregnancy in Minors***

Over the last several years, states have expanded minors' authority to consent to prenatal care.<sup>30,99</sup> The majority of states and the District of Columbia permit minors to receive confidential prenatal care and routine labor and delivery services.<sup>28</sup> State or local law may include qualifications or conditions, such as a minimum age for the minor to give valid consent or allowing healthcare providers to inform parents that their minor daughter is receiving services if the provider deems it in the minor's best interests.<sup>31,99</sup> Facility policy should include state-specific law regarding the legal ability of a pregnant minor to consent to obstetric anesthesia.

### ***Maternal-Fetal Conflict***

Although rare, there are situations in which a patient may refuse consent for anesthesia (e.g., refusal for an emergency cesarean delivery) that may jeopardize the mother's and her fetus's health or life.<sup>31,35</sup> In these situations, an anesthesia professional may be caught in an ethical conflict between the principles of beneficence (promoting patient well-being and doing no harm) and respect for the mother's autonomy.<sup>31,35</sup> While some court decisions have ruled to protect fetal rights, others have ruled in favor of the mother's autonomy.<sup>35</sup> When such conflicts arise, the anesthesia professional should respectfully continue to dialogue with the patient in a non-coercive manner and be available should the patient modify her decision. The team references applicable hospital policy and guidelines during the development of a collaborative, dynamic plan to address the rights and safety of the fetus and parturient in a maternal-fetal conflict.<sup>35</sup> An ethics consultation may provide helpful information to address maternal-fetal conflicts.<sup>100</sup> The anesthesia professional should carefully document the informed consent process and the reasons for refusal of anesthesia services.<sup>39,101</sup>

### **Conclusion**

A well-designed and properly executed informed consent process enhances and promotes communication using shared-decision making between the patient and the anesthesia professional. It improves patient safety through patient engagement in the plan of care. Information shared during the process also enhances communication within the healthcare team. The informed consent process includes a patient-centered discussion about the anesthesia care plan, alternatives, and risks and benefits of the anesthesia care plan. The informed consent process is tailored to meet each patient's unique language, health literacy, culture, values, needs, and preferences. Patients have the opportunity to consider anesthesia care options, address concerns, and determine their plan of care. Appropriate documentation of the anesthesia informed consent process is also important to evidence that an effective informed consent process occurred.

## **Appendix: Additional Resources - Patient Communication, Health Literacy, and Cultural Competency**

All content, including text, graphics, images and information, available through these websites is for general informational purposes only. This list is intended to serve as a resource to assist in research regarding patient communication, health literacy, and cultural competency. It is the obligation of the healthcare professional and/or the facility to verify the relevance and accuracy of the information contained in these resources. The AANA has organized these resources, which may be of value to the CRNA in assessing options, but the ultimate obligation to investigate and determine the appropriate course of action rests with the practitioner and facility.

- [National Action Plan for Health Literacy](#)  
The National Action Plan seeks to engage organizations, professionals, policymakers, communities, individuals, and families in a linked, multi-sector effort to improve health literacy.
- [CDC Health Literacy: Accurate, Assessable and Actionable Health Information for All](#)  
This resource provides information and tools to improve health literacy and public health. These resources are for all organizations that interact and communicate with people about health.
- [CDC Clear Communication Index](#)  
This is a research-based tool to help develop and assess public communication materials.
- [CDC Culture and Health Literacy](#)  
This resource provides tools for cross-cultural communication and language access that can help organizations address health literacy and improve communication effectiveness.
- [CDC Resources for Older Caregivers](#)  
This resource provides several tips caregivers can use to help older adults make decisions about their health.
- [The AHRQ Health Literacy Universal Precautions Toolkit](#)  
The Agency for Healthcare Research and Quality (AHRQ) developed the toolkit to improve communication with patients.
- [SHARE Approach Curriculum Tools](#)  
The AHRQ developed shared decision making resources, communication resources, and additional resources to help healthcare providers and patients make the best possible treatment decisions.
- [Guide to Patient and Family Engagement in Hospital Quality and Safety](#)  
The AHRQ developed a guide to help patients, families, and health professionals work together as partners to promote improvements in care.
- [Health Literacy, Health Communication and e-Health](#)  
This resource provides an overview of health literacy, tools, reports/research and related resources.
- [Simply Put, A Guide for Creating Easy-to-Understand Materials](#)  
This guide teaches how to create easy-to-read materials using effective communication and design.
- [MedlinePlus: How to Write Easy-to-Read](#)  
MedlinePlus offers guidelines and resources to help create easy-to-read health materials.
- [PlainLanguage.gov, Improving Communication from the Federal Government to the Public](#)  
This site includes the Federal Plain Language Guidelines.
- [Questions Are the Answers](#)  
This site includes a question builder and short videos of patients and providers sharing the importance of asking questions.
- [Healthy People 2020](#)

This site includes searches on Health Communication and Health Information Technology Objectives.

- [Culture, Language and Health Literacy](#)

Health Resources and Services Administration (HRSA) discusses the role of effective healthcare communication and practices, including health literacy, in improving the quality of services for culturally and linguistically diverse populations as well as people with limited health literacy skills.

- [Promoting Health Literacy Through Easy-to-Read Materials](#)

This class teaches participants to understand various definitions of health literacy and its importance to patient care; to identify factors that may contribute to low levels of health literacy; to be aware of the role of cultural competency in health literacy; to use the basic principles of plain language; and to identify key players in health literacy awareness and advocacy.

- [Cultural Competency and Health Literacy: A Guide for Teaching Health Professionals and Students](#)

This guide is intended to help health professional educators, students, and practicing health professionals to learn how to reduce health disparities and improve health outcomes through culturally-sensitive and effective communication with clients across the health disciplines.

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*Informed Consent in Anesthesia* was adopted by the AANA Board of Directors in 1991 and revised in 2004. In July 2016, the AANA Board of Directors archived that document and adopted *Informed Consent for Anesthesia Care, Policy and Practice Considerations*.