

# Obtaining Consent During the COVID-19 Pandemic - Policy and Procedure

## Policy

As a result of the COVID-19 pandemic, [ORGANIZATION NAME] has transitioned many in-person services to be delivered via our telehealth applications. This is meant as an additional precaution to help keep our employees—including front-line and clinical staff—safe, as well as patients and the broader community. It may also provide the ability to treat a larger influx of patients affected by this disease while maintaining care for those suffering from other sicknesses or ailments.

As part of any service or consultation rendered via telemedicine, clinicians or other staff must obtain informed consent from the patient. This is a legal requirement of a care provider, and it offers the opportunity to educate patients about the services they will receive, associated risks, and the medium through which the services will be administered so they can make the most informed decisions regarding their treatment and health in coordination with their healthcare provider. To help ease the transition of services provided via telemedicine and help further prevent the spread of COVID-19 for any onsite services, verbal consent for treatment will be accepted in lieu of written consent. Documentation of verbal consent is still necessary to provide both the clinician and patient protection should any issues arise in the future.

This temporary policy expansion is similar to obtaining verbal consent when an emergent patient cannot sign a consent form but is capable of consenting to treatment. ***This is not a permanent policy change. This guidance applies only to consent form signatures during the COVID-19 emergency period.***

## Relevant Regulations

**Federal Law:** Should the president declare a disaster or national emergency under the Stafford Act or National Emergencies Act and the Secretary of the U.S. Department of Health and Human Services (HHS) also declares a public health emergency under Section 319 of the Public Health Service Act, certain actions may be taken. For example, under section 1135 of the Social Security Act, certain Medicare, Medicaid, and Children's Health Insurance Program (CHIP) requirements may be waived on a temporary basis. Under this waiver and the Coronavirus Preparedness and Response Supplemental Appropriations Act, verbal consents are allowed and required for virtual check-in services, especially.

**State Law:** [This is an example only. Fill in relevant information for the state(s) in which your organization provides care and consult legal counsel.] While Indiana state law requires informed consent to be obtained for telemedicine services, it does not specifically require separate written consent from the patient.

## Scope

During the COVID-19 emergency period, providers delivering services either in person or through telephonic, virtual, or videoconferencing means are permitted to obtain verbal consent and verbal treatment plan agreements provided they are adequately

documented in the EHR. Verbal consent will be expected to be obtained either prior to the encounter, such as by pre-registration staff, or during the encounter, such as by the clinician providing a telehealth service.

## Definitions

**Informed Consent:** Represents a conversation between a patient and their healthcare provider regarding potential or planned services, their purpose, potential outcomes, as well as the potential risks and benefits associated with those services, and for which the result is the patient noting that they understand those elements and still agree to receive those services.

**Verbal Consent:** This comprises the individual obtaining consent (a healthcare provider or representative) by reading or explaining a verbal version of the consent to treatment form or its key elements in place of providing a written document to the patient and/or obtaining their physical signature. It is just as important to document verbal consent as it is written consent.

**Telehealth/Telemedicine:** As defined by the Health Resources and Services Administration, telehealth utilizes electronic information and telecommunications technologies to support long-distance clinical healthcare, patient and professional health-related education, public health and health administration.

## Procedure:

### I. Obtaining Verbal Consent for Telehealth Services

Given that a telehealth visit, and the processes surrounding it, often occur solely by electronic and virtual means, it presents the opportunity for the patient to be presented with an electronic version of the form that can be signed and copied, scanned, or faxed back. This may allow for the obtainment of written consent without the concern of the transfer of COVID-19. If there is not enough time prior to the service, or the patient is not able to or does not ultimately sign the relevant form, staff will work to obtain verbal consent as outlined below and in subsequent sections.

**Before the Visit:** As the time-to-appointment permits, there will be an attempt to direct the patient to an online version of the consent form and/or a link to a page within the patient portal that explains the key elements of a telehealth service, the technology used, and the associated benefits or potential risks of this medium of service delivery.

- A. As is feasible, pre-service staff will share the consent form, and other forms as deemed necessary, with patients scheduled for telehealth services electronically (e.g., through the patient portal or email). They will ask the patient to sign and send back a copy of the same document via a photo, scan, or fax prior to the start of their service.
- B. If sending the form is not possible prior to the service, or does not occur, pre-service staff will then provide patients with a link to the webpage provided by [ORGANIZATION NAME] explaining verbal consent, how telehealth services are conducted, the technology utilized, and other relevant information.
- C. Consent or refusal thereof must be recorded in the patient's medical record with a signature by the individual receiving verbal consent (see the subsequent section on "Documenting Consent").

**During the Visit:** While this policy does initiate a written consent if time permits, in the current environment, it is likely that consent forms provided electronically may not be seen, will not be filled out or signed, or will not ultimately be received by the organization in time for the service. For that reason, the clinician(s) administering the telehealth appointment will need to confirm whether the patient has provided consent or if verbal consent still needs to be obtained.

- A. In order to fulfill the requirements of this discussion from the perspective of key stakeholders, such as regulatory bodies, payers, and patients, representatives initiating the telehealth service should:
  1. Explain the risks and benefits of accessing services virtually.
    - a. Example benefits include the ability to remain at home, more efficient evaluation and care, and increased access to a specialist or other provider.
    - b. Example risks include the potential for services to be interrupted if equipment or technology fails, the potential of in-person services needing to be scheduled to confirm or further evaluate the patient or their condition, and the potential of a data breach despite having security protocols in place that are regularly tested and updated.
  2. Providers are required to state the type of technology utilized to conduct the service, including the videoconferencing technology.

3. State any limitations of the treatment provided given that it is being conducted virtually.
4. Inform patients of their rights, such as the ability to stop or refuse treatment at any time during the visit.
5. Inform the patient how to proceed if they are disconnected at any point during the visit.

**Documenting the Consent:** Any forms utilized or filled out by staff on behalf of the patient should be attached to the patient record. A summary of the verbal consent should be included as part of an encounter or progress note within the patient record.

- A. Within the encounter note, state the key elements of the discussion:
  1. Include a statement that the service was provided via telehealth.
  2. If the visit was changed from an in-person visit to a telehealth visit, state the reason why (such as to lower the risk of exposure or spread of the COVID-19 virus).
  3. State the type of technology used to conduct the visit.
  4. State the location of the patient and the provider.
  5. State the role played by other participants of the call or videoconference, if applicable.
- B. The representative receiving consent must provide their signature.
- C. Continue to store consent forms as required by security and consent policies already in place at [ORGANIZATION NAME].
- D. It will not be necessary to gather retroactive signatures once the COVID-19 emergency period ends as long as it was documented appropriately and attached to each patient account for each visit.

## II. Obtaining Verbal Consent for Non-Telehealth Services

**Consent by Phone:** Even when verbal consent is obtained from a patient not physically on-site, a signature is still required by the staff member receiving the consent to appropriately document its occurrence. For this reason, it is recommended that staff use the consent form to talk through each component of consent when obtaining it over the phone.

- A. First, inform the patient or individual that the call is being recorded, as applicable.
- B. Identify all parties on the line, including any other family members, and establish their relationship to the patient; determine whether it is the patient (e.g., that they are at least 18 years of age) or a guarantor that will have the authority to consent to the service(s).
- C. Introduce any other organization representatives or care providers on the line as well and their purpose for joining the call.
- D. Explain that you are obligated by state and federal law to ensure you have their consent for treatment prior to services and that they have the right to refuse treatment at any time.
- E. Explain that you are going to read through the consent form and ask the patient/guarantor to acknowledge each statement.
- F. The patient should be given ample opportunity to ask questions.
- G. Once all patient questions are answered, ask the patient if they consent to the service and communicate that you are documenting their consent per regulatory guidelines.
  1. Write the patient's name in the signature line with an added note that consent was obtained verbally and over the phone.
- H. Consent or refusal thereof must be recorded in the patient's medical record with a signature by the individual receiving verbal consent.
- I. If a revenue cycle staff member is not available to perform this procedure, a clinical provider can follow this procedure and document verbal consent.

**In-Person Consent:** Although staff will be obtaining verbal consent from on-site patients to avoid the passing of COVID-19 through pens or paper, a signature is still required by a staff member to appropriately document informed consent was received. For this reason, it is recommended that staff show the form to the patient while explaining its key statements.

- A. Explain that you are obligated by state and federal law to ensure you have their consent for treatment prior to services and that they have the right to refuse treatment at any time.
- B. Explain to the patient that you are going to read through the consent form but will not ask them to touch it. Point to the relevant items as they are mentioned and ask them to verbally acknowledge each statement.

- C. The patient should be given ample opportunity to ask questions.
- D. After the form is shown and discussed, ask the patient if they consent to the service and communicate that you are documenting their consent per regulatory guidelines.
  - 1. Write the patient's name in the signature line with an added note that consent was obtained verbally on-site.
- E. Consent or refusal thereof must be recorded in the patient's medical record with a signature by the individual receiving verbal consent.
- F. If a revenue cycle staff member is not available to perform this procedure, a clinical provider can follow this procedure and document verbal consent.

*COVID-19 is an ongoing situation and organizations' processes are changing daily to adapt to various needs during this crisis. As such, this information is up-to-date as of April 6, 2020. HBI is continually monitoring the situation and updating material as we gather additional information. While HBI has attempted to ensure the accuracy of research provided in this document, the information has been obtained from numerous resources. Therefore, HBI cannot guarantee its accuracy and is not liable for any claims or losses that arise from errors or omissions within this document.*

# Appendix A - Scripting

This policy and procedure represent the requirements and expectations of front-end and clinical staff initiating and obtaining consent for telehealth services or verbal consent for any treatment. All of the requirements listed above must be met to maintain compliance with relevant regulations and organization policy. The following may help staff to better understand how to speak to a patient and ensure all such requirements are met.

*Pre-service staff can initiate written consent for telehealth services by sending relevant documents and stating the following:*

A: Because you will be consulting with a clinician via our telehealth option, we're asking you to document your consent to receive treatment before that appointment. I will be electronically sending you this form to review prior to your visit. This form will explain what consent means and describe your rights as a patient. As such, we ask that you review it carefully, write your initials by each statement, and sign the document and send it back to us prior to your service date.

*Pre-service staff or point-of-service staff can initiate verbal consent for treatment over the phone by stating the following:*

This call is being recorded for quality and compliance assurance. Are you at least 18 years of age, or do you have a parent or guardian that can provide consent for the services you will be receiving from [ORGANIZATION NAME]?

Ok, great. We are required by state and federal law to obtain your consent prior to rendered services. Given our efforts to help stop the spread of COVID-19, we are obtaining that consent over the phone at this time instead of in person or by having you sign a physical form. I'm going to talk you through the key components of the document that you would normally sign, and as I read each statement, I will ask you to acknowledge whether you agree or do not agree. Then I'll see if you have any questions.

[Read each statement on the form separately, pausing to hear the patient state they understand or agree.]

Do you have any questions at this point that I can help answer?

Great, thank you. I will make a note within your record that you gave me your verbal consent over the phone and date it. Do you permit me to do so?

Thank you, [Name]. [Proceed with processes or services].

*Pre-service staff or point-of-service staff can initiate verbal consent for treatment in person by stating the following:*

We are required by state and federal law to obtain your consent prior to rendered services. Given our efforts to help stop the spread of COVID-19, I am going to show you the consent form, but I will ask you to not touch or sign it for your own safety and well-being. I'm going to talk you through the key components of the document that you would normally sign, and as I read each statement, I will ask you to acknowledge whether you agree or do not agree. Then I'll see if you have any questions.

[Read each statement on the form separately, pausing to hear the patient state they understand or agree.]

Do you have any questions at this point that I can help answer?

Great, thank you. I will make a note on this document that you gave me your verbal consent on this date. Do you permit me to do so?

Thank you, [Name]. [Proceed with processes or services].

*Clinicians beginning a telehealth visit can use the following as a guide. These items must be stated prior to any evaluation or other telehealth services if consent to treatment has not already been obtained:*

A: Before we begin, I am obligated by state and federal law to ensure I have your consent for treatment. The service(s) I will perform during this session may include consultation, diagnosis, treatment, or referral to other care or resources. The information you provide to me may be used for diagnosis, therapy, follow-up care, or to provide you with some education or recommendations.

[ORGANIZATION NAME] utilizes videoconferencing for its telehealth visits. This means we will be communicating with live, two-way audio and video. We may discuss or share specific medical information, such as test results or X-rays. We store this information just like we would any clinical documentation in your medical chart—we use the same security protocols to keep this information safe. Only authorized users will be able to access it without your written consent.

*[If anyone else is on the call/video, state who from the organization or likewise ask the patient to state their counterpart's presence, title/relationship, and purpose for being there. Ask the patient if they permit them to be involved in the session.]*

I hope in accessing these services virtually today that this is allowing you to stay at home, that you didn't need to wait as long as you might have at our facilities, that we can get you evaluated efficiently, and that we are helping to fit into your schedule.

However, it is always possible that this technology could fail or our connection could be lost. Sometimes the quality of the consultation or equipment used may not be as good as in person, and a follow-up appointment may need to be scheduled to confirm or further evaluate your symptoms. As mentioned, we have a variety of network and data safeguards in place, but there is still the rare possibility this session or resulting information could be breached.

By consenting, you also agree not to use this in place of visits with your primary doctor, acknowledge you were given the choice to choose your care provider today, and understand that you may request copies of your medical records.

Do you still wish to proceed?

Great, thank you. I will make a note within your record that you gave me your verbal consent over videoconference, and date it. Do you permit me to do so?

Great, thank you. And should we get disconnected, you can call [XXX-XXX-XXX] or email [ ]@ [ ].

Now, if at any point you wish to stop this service or refuse treatment, that is part of your patient rights. We cannot provide urgent or emergency care through these means, so if you or I believe that you are experiencing a medical emergency, it would be best to call 911 or go to your nearest urgent care center or ED. I would help you understand the best course of action.

Do you have any questions for me on any of this information? *[If the patient does ask any questions, confirm after your response that you have satisfied each question at hand].*

*[Proceed with clinical evaluation/service]*