Form

Approved

OMB No. 0920-New
Expiration Date: XX/XX/XXXX

Using Real-time Prescription and Insurance Claims Data to Support the HIV Care Continuum

Attachment 8b

Verbal consent – provider participants

Verbal consent – provider participants

Healthcare provider information

Provider credential:
Provider name:
Provider specialty:

Clinic information

Provider's clinic name:
Clinic phone number:
Clinic county:
Clinic health district:

As I said before, my name is [Linkage Coordinator's name]. I'm calling on behalf of Virginia Medicaid about a quality improvement research study for Medicaid members and their providers. The purpose of the initiative is to evaluate patient referrals and provider prescribing support for Medicaid members with late antiretroviral therapy (ART) prescriptions.

Can I tell you more about it?

- ◯ Yes
- ◯ No
- ◯ Not now

No, not interested

I understand. If you would like to hear more about the study, you can call me back at [Linkage Coordinator's phone number]. Thank you for your time.

End call.

Call end time

* must provide value

Now H:M

Notes (optional)

Expand

No, not available right now

Is there another time that would better for you?

Offer to schedule a time to call back, or provide contact number and business hours for participant to call back.

- ◯ Yes
- ◯ No

Alternative time identified

Schedule alternative call.

* must provide value

M-D-Y

Click to identify day for alternative call.

H:M

Click to schedule time for alternative call.

Thank you. I appreciate your time. I will call you back at [provider's phone number] on [scheduled date] at [scheduled time].

End call.

Call end time

* must provide value

Now H:M

Notes (optional)

Expand

Submit

Alternative time not identified

I understand. Thank you for your time. If you would like to learn more about the study, you can reach me at [Linkage Coordinator's phone number]**.**

End call.

Call end time

* must provide value

Now H:M

Notes (optional)

Expand

Available

As I said before, my name is [Linkage Coordinator's name]. I'm calling on behalf of Virginia Medicaid about a quality improvement research study for Medicaid members and their providers. The purpose of the initiative is to evaluate patient referrals and provider prescribing support for Medicaid members with late antiretroviral therapy (ART) prescriptions. I'd like to tell you more about the study to see if you would like to participate.	
It will take 8-10 minutes to describe the study. I must tell you about the study if you want to participate. You can interrupt me to ask questions or to take a break at any time. You can also stop me to end this call at any time.	

The research study is to learn about challenges to and support for filling antiretroviral therapy (ART) prescriptions. The research is being done as part of a quality improvement initiative at Virginia Medicaid. Virginia Commonwealth University (VCU) is implementing the study on behalf of Virginia Medicaid. Virginia Medicaid and VCU are working together to learn about challenges that Virginia Medicaid members have in taking their prescribed medication. Specifically, we are implementing and evaluating a program called Antiretroviral Improvement among Medicaid enrolleeS (AIMS). This program is designed to support members and their providers in filling ART prescriptions. We think this support may increase how often ART prescriptions are filled and increase HIV viral suppression.

The Virginia Department of Health, University of Virginia, the Centers for Disease Control and Prevention, and the National Institutes of Health are also study partners. The study is funded by the Centers for Disease Control and Prevention and the National Institutes of Health.

We are asking you to be in this research study because you may have a patient who is living with HIV but has not previously filled a prescription for antiretroviral therapy (ART). We believe this because there is no record of having ever filled an ART prescription.

Participating in this research study is voluntary. You do not have to participate unless you want to. If you do participate, you can withdraw at any time. There is no penalty of any kind if you withdraw or decide not to take part. Your decision not to take part or to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled. If you don't want to take part, you still have access to support that can help with prescribing ART. We can provide you some information for support, even if you choose not to take part, at the end of this call.

If you decide to take part in this research study, you will be asked to take part in some phone calls and to give permission for us to collect information related to these calls. You will receive provider support through a one-time consultation with a peer clinician. The peer clinicians are HIV specialist clinicians in Virginia who are state leaders in HIV clinical care and who have a high volume of patients living with HIV. The consult will involve peer mentoring, education, and resources tailored to your needs. The consult may involve discussion of ART clinical guidelines, strategies to optimize ART adherence, and resources for clinical management and supporting people living with HIV. You may be asked other questions, such as about your medical specialty. Your responses to questions will be documented and we will collect information on barriers to HIV prescribing and recommended resources. The consult will take about 30 minutes and will be scheduled at a time that is convenient for you; the consult will not be audio- or video-recorded. A study team member may provide information about the peer clinician's recommended resources after the consultation. Any recommended resources will be tailored to your individual needs. We will also collect quality of care information, such as medication adherence, and health outcomes, such as HIV viral suppression, from your patient(s) who agree to participate in this study. Not all providers of patients without a record of a prior ART prescription will be asked to participate. Only providers who have also been designated as eligible have been asked to participate.

None of the resources to which we will connect you are experimental. The resources are existing resources available through professional organizations, nationally recognized HIV curricula, and guidance from the CDC. We also may provide resources, such as from Virginia Medicaid managed care organizations, that you could reference to help your patients. We will provide you with these resources only if you give us permission to do so.

It is possible that you may find some questions difficult or uncomfortable to answer. Some questions you may not wish to answer. If so, just tell me and we will go to the next question. These questions are about potential barriers to ART prescribing.

There is a risk that you may feel upset or embarrassed if you talk about barriers to prescribing an ART prescription or about caring for people living with HIV. There are no other known physical, financial, social, or legal risks associated with the study.

There are potential benefits to participating in this research study. This study could help you, but that cannot be guaranteed. The study may help you think through challenges to ART prescribing or providing HIV clinical care. The study may also help connect you with resources that address these challenges.

Together, these may help your patients fill their ART HIV prescriptions and take their ART medication more consistently.

support. You will not have to pay to use any resource(s) that we connect you with.

Your participation in this research study will involve about 30 minutes total of your time. This includes time on the phone calls with peer clinicians. It does not include time you may spend to connect to and get support from resources that you've connected with.

You will not be compensated for participating in this research study. You will be connected to resources to provide support. You will not have to pay to use any resource(s) that we connect you with.

Your participation in this research study will involve about 30 minutes total of your time. This includes time on the phone calls with peer clinicians. It does not include time you may spend to connect to and get support from resources that you've connected with.

About 1,000 members and 40 providers will participate in this study.

It will take me just a few more minutes to describe the study. Can I answer any questions right now?

Expand

As I said, it will take me just a few more minutes to describe the study. You can interrupt me to ask questions or to take a break at any time. You can also stop me to end this call at any time.

We will keep your information confidential and securely stored by limiting who will be able to access your private information. The CDC and the National Institutes of Health, which are study partners, will not have access to information that can be used to personally identify you. Your data will be stored on a secure Virginia Medicaid server.

This study has something called a Certificate of Confidentiality from the federal government to make sure we can best protect your privacy. The certificate means that we cannot be forced to tell people about your participation, even if we are asked by courts or police.

However, sometimes we cannot keep your information or participation confidential. If we find out that keeping your information or participation private could put you or someone else in danger, we may have to tell agencies to protect you or another person. Researchers may also have to give your information if the study is audited.

Personal information about you might be shared with or copied by authorized representatives from the following organizations for the purposes of managing, monitoring and overseeing this study:

- **The study Sponsor, representatives of the sponsor and other collaborating organizations**
- **Representatives of VCU and the VCU Health System**
- **Officials of the Department of Health and Human Services**

We will not publish your identifiable information or present it to the public. At the end of the study, we will tell you the results and explain what they mean. However, we will not provide to each participant their individual research study results or outcome of their individual patient participants.

The information collected as part of this study will not be used or distributed for future research studies, even if identifiers are removed.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

I want to make sure that any questions you have are answered. I can answer any questions you may have right now. Dr. April Kimmel, the principal investigator evaluating the study, and other study staff can also answer your questions. They can be reached at [study email**] and [**study phone number**].**

If you think that you have not been treated fairly in the study, you can contact Dr. Kimmel and the study staff. You can also call VCU's Office of Research and Innovation at (804) 827-2157.

Do you have any questions now that I can answer?

* must provide value

- (●) Yes
- ( ) No

Questions from eligible participants

Record any questions from participants.

Expand

Questions to assess understanding of study

I really appreciate your time so far. It's important to me that you understand the study and your rights as a participant.

I'd like to ask you some questions to be sure that I have been clear.

I'm going to read you 6 statements about this study to be sure that I have been clear. Please indicate 'true' or 'false' after each statement.

This quality improvement research study is about understanding challenges to filling and prescribing ART prescriptions. It is also about how support can help with these challenges.

* must provide value

- (●) True
- ( ) False

You do not have to participate in this research study.

* must provide value

- (●) True
- ( ) False

If you participate, you may be provided information about resources that can address certain challenges in ART prescribing and HIV clinical care. You will not receive compensation for participating.

* must provide value

- (●) True
- ( ) False

If you participate, you can withdraw at any time and for any reason. You can skip any questions that you do not want to answer.

* must provide value

- (●) True
- ( ) False

There will be no penalty of any kind if you decide not to participate or to withdraw from the research study.

* must provide value

- (●) True
- ( ) False

The study team cannot use your information unless you give permission to use it. We cannot be forced to tell someone you participated in the study.

- (●) True
- ( ) False

* must provide value

Note: if the answer to any of the above items is false, the following text will populate:

Actually, that's true: (repeat item).

Discuss with participant to ensure comprehension before moving on.

Thank you so much. Now I'm going to ask you if you consent to participate in this study.

(End consent questions)

Consents

Do you consent to participate in this research study?

* must provide value

- (●) Yes
- ( ) No

Consent date and time

* must provide value

Now M-D-Y H:M

Move on to scheduling form.

Does not consent

Do you consent to participate in this research study?

* must provide value

- ( ) Yes
- (●) No

I understand. May I provide you with information on any resources that could support ART prescribing? These resources include contact information for specific MCO health benefits, HIV provider educational resources, and/or HIV clinical care peer mentoring and consultations. [check all that apply]

* must provide value

- ( ) Contact info for MCO health benefits
- (●) HIV provider educational resources
- ( ) Peer mentoring, consultation
- ( ) No resources requested

If 'Contact info for MCO health benefits':
Fax list to provider fax number

If 'HIV provider educational resources:'
HealthHIV National HIV Curriculum: https://healthhiv.org/

If 'Peer mentoring, consultation:'
National Clinician Consulting Center: http://nccc.ucsf.edu/clinician-consultation/

or

AAHIVM: http://community.aahivm.org/mentoring

If you would like to hear more about the study, you can call me back at [Linkage Coordinators' phone number]. Thank you for your time.

End call.

Call end time * must provide value		Now	H:M	
Notes (optional) *Record any questions from participants.*				Expand