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 8a

Verbal consent – participants

Verbal consent – participants

Eligible potential participant information

Name:
DOB:
ID:
Phone:

Not Interested

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 and [name of member's Medicaid Care Organization] members. I'd like to tell you more about the study to see if you would like to participate. Can I tell you more about it?

- ○ Yes
- ◉ No
- ○ Not now

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 (post-call)

Record any questions from participants.

Expand

Not Available Right Now

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 and [name of member's Medicaid Care Organization] members. I'd like to tell you more about the study to see if you would like to participate. Can I tell you more about it?

- ○ Yes
- ○ No
- ◉ Not now

Alternative time identified

I understand. It would be great to tell you more about the study. Would you be available to talk a different time?

* must provide value

- ◉ Yes
- ○ No

Schedule alternative call.

* must provide value

26-05-202 D-M-Y

Click to identify day for alternative call.

11:45 H:M

Click to schedule time for alternative call.

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

End call.

Alternative time <u>not</u> identified

I understand. It would be great to tell you more about the study. Would you be available to talk a different time?

* must provide value

- ○ Yes
- ◉ No

I understand. I will try calling you again a different time. You can also call me back at [Linkage Coordinator's phone number] during [Linkage Coordinator's working hours]. Thank you and I look forward to talking with you a different time.

End call.

End Call

Call end time

* must provide value

Now H:M

Notes (post-call)

Record any questions from participants.

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 and [name of member's Medicaid Care Organization] members. I'd like to tell you more about the study to see if you would like to participate. Can I tell you more about it?	◉ Yes ○ No ○ Not now
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 about taking your prescribed medication and staying healthy. 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. To do this, we are implementing and evaluating a program called Antiretroviral Improvement among Medicaid enrolleeS (AIMS). This program is designed to support members to fill HIV prescriptions. We think this support may increase how often HIV prescriptions are filled and hope that the AIMS program can improve your health 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 missed an HIV prescription fill. We believe this because there is no insurance record for an HIV prescription that was expected to be filled.

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 from your healthcare providers, pharmacists, and health plan, along with community support services. We can provide you information for these supports even if you choose not to take part.**

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 your health information:

1) The study will involve two or three phone calls. The phone calls will be with me or another member of the study team. Calls will last about 30 minutes each and occur about 4-8 weeks apart. The number of calls will be based on your needs and availability. For example, we might have three calls if we need to reschedule a call, if I need to follow-up with you, or if it seems like you need additional support.

2) In these phone calls, I will ask you questions about how you receive healthcare and fill prescriptions. We will have a conversation about challenges to filling your HIV prescriptions, and we will think together about different ways to support you in filling your HIV prescriptions. We will record information about how you receive your healthcare, fill prescriptions, and challenges you have in filling prescriptions.

3) In our phone conversations we will connect you to resources. Based on our conversation and your preferences, I will make some recommendations about resources that can support you in filling your HIV prescription(s) based on your own individual needs. These resources might involve your health plan, your provider, your pharmacy, or specialized resources in the community. For example, if you are having difficulty picking up your medication, we might connect you to your health plan that can help set up mail-order prescriptions. Or if you feel that you do not have an adequate support system of other people living with HIV, we might connect you to a community organization that can provide support. This may also include mental health support, in which case we would connect you to your health plan or other community resources to support you. When we connect you to a resource, we will call together (for example, on a three-way call). To protect your privacy, we will never provide your information to a resource, or third party; only you will provide personal information to resources we call. We may also give you contact information for resources that can provide additional support and might follow-up to make sure you were able to get what you needed from the resource. We might also follow-up with you if our records indicate an HIV prescription has not been filled.

4) **We will also ask you to agree to have some of your health information from Virginia Medicaid insurance records and health information that is routinely reported to the Virginia Department of Health be shared with the study team so we can understand how this quality improvement research program improves your health.**

None of the resources to which we will connect you are experimental, but the program to connect you to these resources is. The resources are existing resources available through your provider, your pharmacy, your health plan, or the community. The experimental program is designed to help connect you to these resources.

During the phone calls, 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 whether you've filled your HIV prescriptions and, if not, some of the reasons why.

There is a risk that you may feel upset or embarrassed if you talk about barriers to filling an HIV prescription. There is a risk that you may feel upset that you don't have the chance to receive all possible referrals and resources available through the study. However, we will work together with you to identify the resources most important to you and make referrals based on your preferences. There are small social or legal risks of unauthorized or unintentional disclosure of your HIV status. This risk is no greater than disclosure by a medical professional. We take many precautions to prevent this from happening, including implementing protocols on who can access to your health information, how it is stored and accessed, and verifying your identity during study procedures. There are no other known physical, financial, social, or legal risks associated with the study.

There are some 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 filling your HIV prescriptions. The study may also help connect you with resources that address these challenges. Together, these may help you fill your HIV prescriptions and take your HIV medication more consistently.

You will not be compensated for participating in this research study. You will be connected to resources to provide support. We do not anticipate that you will have to pay to use any resource(s) that we connect you with. However, for some resources, you may have to pay for transportation to reach a resource.

Your participation in this research study will involve about 2 hours total of your time. This includes time on the phone calls and time connecting you to resources. It does not include time you may spend to get support from resources that you've connected with.

Not all participants in the study will receive the same support or in the same way. You have been selected to receive support in the way I described earlier based on characteristics of your health provider and our insurance records of how you have filled your HIV prescriptions. Other participants will be offered different resources.

As I said before, participating in this quality improvement research study is voluntary. If you decide not to participate in this study, you will receive the same Medicaid benefits that you would receive if you were not in the study. If you decide not to participate, it will not affect your relationship with your medical providers or your medical care. If you decide not to participate or contribute your health information, you will not be referred to resources by our study evaluation team.

About 1,000 members 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?

Record any questions from participants.

Expand

As I said, it will take me just a few more minutes to describe the research 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.

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 address] 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 HIV prescriptions. It is also about how support can help with filling HIV prescriptions.

* 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 connected to resources that can address certain challenges in filling your HIV prescription(s). 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

If you decide not to participate or to withdraw, your benefits from [name of member's Medicaid Care Organization] will not change. The care you receive from your doctor will not change.

* 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 research study.

* must provide value

- (●) Yes
- ( ) No

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.

Consents

Do you consent to participate in this research study?

* must provide value

- ◉ Yes
- ○ No

Consent date and time

* must provide value

Now Y-M-D H:M

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 you in filling your ART prescription? These resources include contact information for your provider, pharmacy, health plan, and/or community support. [check all that apply**]**

* must provide value

- ○ Provider
- ◉ Pharmacy
- ○ Health plan
- ○ Community resources (Status Neutral Program)
- ○ No resources requested

reset

If 'Contact info for provider':
[provider name], [provider practice], [provider phone number]

If 'Contact info for pharmacy':
[pharmacy name], [pharmacy phone number]

If 'Contact info for health plan':
[member's Medicaid Care Organization] [Medicaid Care Organization phone number]

If 'Contact info for community support':
[Status Neutral Service Navigation program phone number]

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 (post-call)

Record any questions from participants.

Expand