

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 8c

Verbal consent - control participants

Public reporting burden of this collection of information is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; Attn: OMB-PRA (0920-New)

Verbal consent - control participants

Eligible potential participant information

Name:

DOB:

ID:

Phone:

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?

- Yes
 No

* must provide value

Schedule alternative call.

* must provide value

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||

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 not identified

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

- Yes
 No

* must provide value

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

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, including through the Status Neutral Service Navigation Program available through the Virginia Department of Health. The Status Neutral program provides high-impact service navigation services, including referrals to support services, to Virginians living with HIV. 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 give permission to use your health information from Medicaid insurance records, including medical services and filled prescriptions. You will also be asked to give permission to use health information from public health surveillance for lab tests. Nothing further will be asked of you.

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. 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.

Your participation in this study is unlikely to benefit you personally. We think that your health information will help us to learn more about member adherence to HIV medication, how to promote your health, improve member support through Virginia Medicaid benefits and services, and prevent HIV transmission.

You will not be compensated for participating in this research study. If you want, we will provide you the information for your provider, pharmacy, or health plan. You will also have the opportunity to be connected to Virginia Department of Health's Status Neutral Service Navigation program. You will not have to pay to use the Status Neutral program.

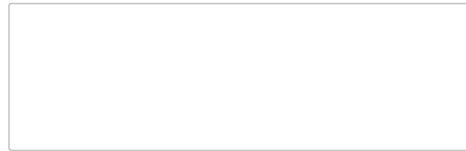
Not all participants in the study will receive the same support or in the same way. You have been selected to receive support in the way I described earlier based on characteristics of your health provider and our insurance records of how you have filled your HIV prescriptions. Other participants will 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 contribute your health information, it will not affect your relationship with your medical providers or your medical care.

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 organizing 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 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?

Yes

No

* must provide value

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 taking HIV medication as prescribed.

* must provide value

- True
 False

You do not have to contribute health information to this study.

* must provide value

- True
 False

You will not receive compensation for contributing your health information.

* must provide value

- True
 False

If you contribute health information, you can withdraw it at any time and for any reason.

* must provide value

- True
 False

If you decide not to contribute your health information, 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 have contributed health information to the research study.

* must provide value

- True
 False

**Thank you so much. Now I'm going to ask
you if you consent to contribute your health
information to this study.**

(End consent questions)

Consents

Do you consent to participate in this research study?

- Yes
- No

* must provide value

Consent date and time

  Now M-D-Y
H:M

* must provide value

Thank you. We appreciate you sharing your health information. We talked earlier about providing you information for resources that could support you in filling your ART prescriptions. These resources include contact information for your provider, pharmacy, health plan, and/or community support, including Virginia Department of Health's Status Neutral Service Navigation program. May I provide you with any of this information? [check all that apply]

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

* must provide value

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]

Call end time

* must provide value

Notes (post-call)

Record any questions from participants.

Does not consent

Do you consent to participate in this research study?

- Yes
- No

* must provide value

Thank you. We appreciate you sharing your health information. We talked earlier about providing you information for resources that could support you in filling your ART prescriptions. These resources include contact information for your provider, pharmacy, health plan, and/or community support, including Virginia Department of Health's Status Neutral Service Navigation program. May I provide you with any of this information? [check all that apply]

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

* must provide value

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]. Thank you for your time.

End call.

Call end time
* must provide value

<input type="text"/>		Now	H:M
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Notes (post-call)

Record any questions from participants.

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Expand