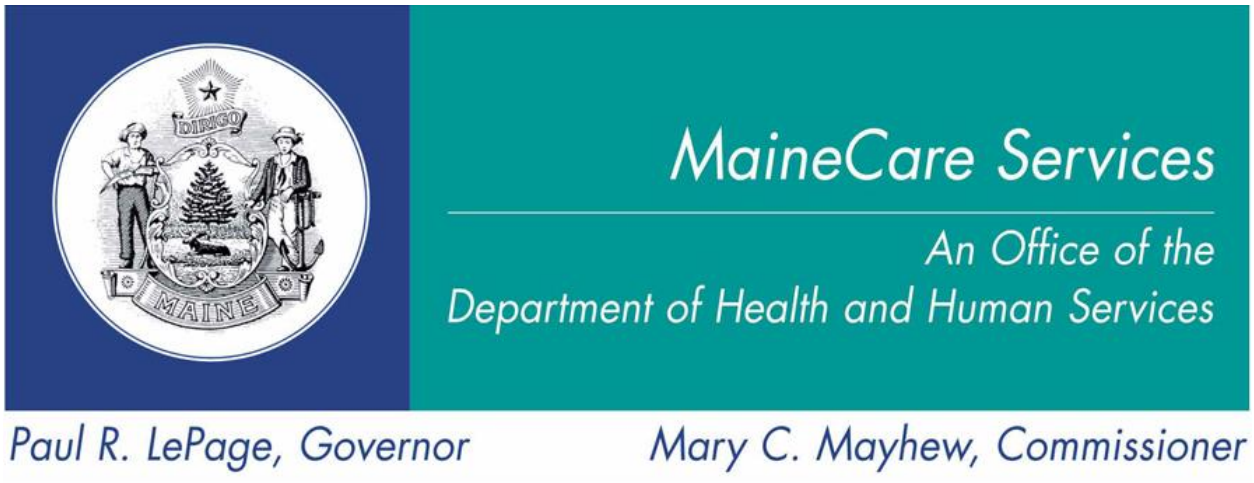


Maine Seal

Quarterly Report

HIV/AIDS 1115 Demonstration Project

SFY 2015 Quarter 1

DY 12 Quarter 4

(10/1/14 - 12/31/14)

MaineCare Services
An Office of the
Department of Health and Human Services
Paul R. LePage, Governor Mary C. Mayhew, Commissioner
Maine Seal

Department of Health and Human Services
MaineCare Services
Nurse Coordinator
11 State House Station
Augusta, Maine 04333-0011
Tel.: (207) 287-4758; Fax: (207) 287-1864
Toll Free (866) 796-2463; TTY Users: Dial 711 (Maine Relay)

February 27, 2015

Iris V Allen, MPH
Division of State Demonstrations and Waivers
Center for Medicaid and CHIP Services, CMS
Mail Stop S2-01-16
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Dear Ms. Allen,

Please find enclosed, the quarterly report for the Maine HIV/AIDS Section 1115 Demonstration Waiver for the quarter ending 12/31/14. Please contact Emily Bean at 207-624-4005 if further information is needed.

Sincerely,

Stefanie Nadeau, Director
Office of MaineCare Services
11 State House Station, Augusta, ME 04333-0011
Phone: 207-287-2093

cc: Kathryn Holt, CMS Boston
Kevin Flanigan, MD
Sheena Bunnell, PhD

Maine HIV/AIDS Demonstration

Section 1115 Quarterly Report

Demonstration Year: 12 (01/01/2014 - 12/31/2014)

Demonstration Quarter: 4 (10/01/2014 - 12/31/2014)

Maine Fiscal Quarter: 2/2015 (04/01/2015 - 06/30/2014)

Introduction

The MaineCare HIV/AIDS 1115 Demonstration project has completed the fourth quarter of its twelfth year. This demonstration was implemented on July 1, 2002 and has been approved through December 31, 2015. The goal of the demonstration is to provide critical services to people living with HIV/AIDS in order to delay, prevent, or reverse the progress of their disease.

Enrollment Information

During the fourth quarter of the twelfth year, there were 794 total MaineCare and demonstration members enrolled in the demonstration project.

Enrollment Counts

There were 484 demonstration enrollees included in the quarter. These members qualified by having a diagnosis of HIV/AIDS and income at, or below, 250% of the Federal Poverty Level (FPL). There were 340 Medicaid members included in the quarter. Medicaid members are identified as either the original cohort of members who are receiving MaineCare, or MaineCare members where 25% or more of their Medicaid claims are HIV-related.

Demonstration Populations (as hard coded in the CMS-64)	Count of members enrolled at Start of Quarter	Count of members enrolled During the Quarter	Number of Persons Disenrolled during Quarter for non-payment of premiums*	Number of Persons Disenrolled during the Quarter**	Number of Members that Changed FPL	Members that Switched Rate Codes	Count of members enrolled at End of Quarter
Enrollees at or below 100% FPL Demonstration Enrollees	172	198	0	(16)	(9)	(0)	173
Enrollees above 100% FPL Demonstration Enrollees	272	286	0	(3)	(12)	(0)	271
Members HIV Positive and MaineCare Eligible	324	340	0	(24)	N/A	(4)	316
Totals	768	824	0	(41)	(21)	(4)	760

Note: The numbers in the above chart come from different data sources; therefore they may not reflect accurate enrollment counts as they are based on FPL.

*Enrollees who fail to pay premiums within the 60-day grace period could lose coverage until premiums are paid. If the coverage is reinstated with no lapse, they will not be considered "disenrolled." (Example: a member has unpaid premiums and their coverage is closed on July 31st. On August 8th, the balance is received and the member is reopened with an August 1st start date. Since the coverage was retroactively opened, they would not be counted as disenrolled).

**Reasons an individual disenrolls could include: moving out of state, going over income, becoming deceased.

Outreach/Innovative Activities

Outreach is ongoing. Methods used for outreach during this period included:

- Attending the monthly Ryan White meeting. People present were case managers, members, providers, and representatives from other various agencies.

- Attending the monthly HIV Advisory Committee (HIVAC) meetings. Present were representatives from case management agencies, the AIDS Drug Assistance Program (ADAP), Maine Center for Disease Control and Prevention (CDC), Office of MaineCare Services (OMS), legislators, people living with HIV/AIDS, and appointed committee members.

- Attending weekly Decision Support System (DSS) User Group meetings to discuss the DSS and system issues, workarounds, and resolutions.

- The Nurse Coordinator making calls to members who had not been contacted in six (6) months or more (see enclosure 5).

- Referring more members to Consumers for Affordable Health Care to help with their unmet healthcare needs/coverage.

- Sending FDA medication alerts to primary care providers regarding Tybost and Vitekta. Alerts are sent via mail or email depending on provider preference (see Attachment A: Outreach).

- Continuing with the new Emergency Department (ED) reporting process that incorporates a daily census from each hospital, in addition to the regular monthly report (which has a two month lag time).

- Sending the program's new authorization form to new members and members whose current form was outdated (see Attachment A: Outreach).

- The Nurse Coordinator and Program Manager attending and presenting at the Positive Living Conference, a conference that is specifically and only for individuals in the state who are living with HIV/AIDS. This conference is put on by the Maine HIV, STD, and Viral Hepatitis Program through Maine CDC. Presentations included: Treatment as Prevention, HealthCare Experts Panel, STD Jeopardy, HIV Services in Maine, Opportunities for Involvement, Mental Health and, Continuum of Care. There was also a presentation by the Special Benefit Waiver Program Manager and Nurse Coordinator that included an overview of the waiver, its goals, what we do and why we call, the differences in the waiver and MaineCare, and some resources.

- The Nurse Coordinator and Program Manager going to Community Health and Counseling Services (CHCS) to meet with the new case manager.

- The Nurse Coordinator and Program Manager attending the Annual Infectious Disease Conference. The keynote speaker was Dr. Nathaniel James, Director, Maine Medical Center's International Clinic. He presented on refugee health: immunizations, HIV, Hepatitis, and Tuberculosis. Other presentations were: HealthInfoNet, Climate Change: Effects on Water and Food Borne Disease, What to do About Ticks, Harm Reduction: Working with Active Drug Users to Prevent Infectious Diseases, and an Ebola Panel pertaining to how Maine is preparing.

- The Nurse Coordinator and Program Manager attending the Health Literacy 202 training sponsored by Maine CDC's Office of Health Equity. The objectives of this training included: analyzing and writing plain language materials, learning about and addressing information needs of particular audiences, analyzing and applying principles of clear visual design, using plain numbers in ways that most adults can

understand and use, and trying creative writing techniques to develop more interesting materials.

Operational/Policy Development/Issues

Co-payments and premiums (for waiver enrollees)

Waiver enrollees pay all of the regular Medicaid co-payments except for:

Physician visit: co-pay is $10.00

Prescription drugs: co-pay is $10.00/30-day supply for generic medications
co-pay is $20.00/90-day supply for brand name medications
(by mail order only)

- The Maine ADAP pays deductibles, premiums and co-pays (for medications on the ADAP's formulary). This coverage wraps around MaineCare, Medicare Part D, and private insurance. The ADAP covers medications to treat: HIV, mental illness, high blood pressure, high cholesterol, hepatitis, diabetes, thyroid disease, heartburn, nausea, diarrhea, antibiotics, contraceptives, estrogen, and vaccines. The full ADAP formulary can be found at: http://www.maine.gov/dhhs/mecdc/infectious-disease/hiv-std/provider/documents/adap-quarterly-formulary.pdf.
- The ADAP assists with co-pays in the following way:
    - The ADAP pays 100% of the co-pay (for formulary medications) for members with MaineCare (up to $10 per 30-day supply).
    - The ADAP pays 100% of the co-pay (for formulary medications) for members with MaineCare and Medicare Part D (up to $5 per 30-day supply as this is the maximum co-pay amount).
- Enrollees with an individual income of 150% of the FPL or higher are required to pay a monthly premium to receive services under the waiver. If a member submits their premium bill to the ADAP, the program will assist them with these payments. Effective June 1, 2014, the premium amounts are as follows:

INCOME LEVEL	MONTHLY PREMIUM
Equal to, or less than, 150% of Federal Poverty Level	0
150.1% - 200% of Federal Poverty Level	$32.59
200.01% - 250% of Federal Poverty Level	$65.17

*Note: premiums are inflated by five percent (5%) annually

- In 2013, there was an eight percent (8%) increase in the number of members who stated they were able to afford their co-pays and premiums.

Financial/Budget Neutrality Development/Issues

Member numbers are based on distinct member paid claims of actual participation (refer to enclosure 3), as compared to the enrollment data that is based on member eligibility. Consequently, the number of members calculated in the financial shell does not match exactly to the number of members enrolled.

The figures reported in enclosures 1 and 2 ("Budget Neutrality" and "Overall Service Costs by Demonstration Year," respectively) come from the Medicaid Program Budget and Expenditure System (MBES) "CMS 64 Schedule C Report for 1115 Waivers." The data from previous quarters is updated in each enclosure with approved adjustments.

ADAP funds spent on MaineCare clients for this quarter can be seen in enclosure 4.

It was discovered in November that the Decision Support System (DSS) was missing financial data from the first and last week's financial cycle for the month of October. The missing lines were identified and re-run in a special extract. The extract was delivered along with the normal month-end data delivery thus restoring all of October's financial data on December 16, 2014.

Member Month Reporting

Eligibility Group by Month	October 2014	November 2014	December 2014	Total for Quarter Ending 12/14
Enrollees	443	445	444	1,332
Members	324	319	316	959

Eligibility Group by Disease Stage	1 - ASX (asymptomatic)	2 - SX (symptomatic)	3 – AIDS	Total for Quarter Ending 12/14
Enrollees	810	418	104	1,332
Members	557	302	100	959

Consumer Issues

The MaineCare Member Services help desk is the first point of contact for all MaineCare members, including those living with HIV/AIDS. Based on our monthly reports from Member Services, there were no complaints this quarter.

There were no complaints received directly by the MaineCare coordinator.

Type	Contact Note	Resolution

Quality Assurance/Monitoring Activity

- Quality indicators continue to be monitored through claims data. These indicators include cost data, number and appropriateness of anti-retroviral medications, hospitalization, physician and ER utilization rates, death rates, compliance with

guidelines on prophylactic medications for opportunistic infections, ophthalmology exams, and pap smear exams, including visits to provider offices.

- One of the waiver's primary roles is to establish a close link with provider offices in order to obtain disease progression data, including CD4 and viral load results that will allow tracking of disease state progression and targeted interventions.

- An adherence report was designed based on our members' prescription pick-up dates. A link has been established between CD4 data and the adherence report to help target interventions. Based on this report, daily calls are made to members to remind them about their prescription pick-up dates. We project that this proactive approach will improve our members' compliance with their anti-retroviral medication. There were 296 adherence calls during the quarter (refer to enclosure 5).

- Member compliance with anti-retroviral medication continues to be tracked via their prescription refills. A link has been established between CD4 data and the compliance report to help target interventions. There are three phases of calls. The first phase is of the greatest concern, where calls are made to members whose CD4 counts are below 200 and they are late picking up their medications. In the second phase, calls are made to members whose CD4 counts are between 200 and 350 and they are late picking up their medications. In the third phase, calls are made to members whose CD4 counts are above 350 and they are late picking up their medications. There were 130 compliance calls during the quarter (refer to enclosure 5).

- Frequent address changes and disconnected phones for this population continue to make it difficult to contact members for adherence and compliance interventions. Ongoing efforts continue by contacting the regional Offices for Family Independence (OFI), case managers, pharmacies, and providers for members' most updated addresses and phone numbers.

- A contact tracking system which includes calls, letters, emails, faxes, complaints, and grievances has been underway since February 6, 2003, with daily data entry by the Nurse Coordinator and Program Coordinator. This system allows us to note the number of calls per day, week, month, and year and gives us a detailed map of calls by contact entity and reason.

- A total of 1,410 contacts were made in this quarter. Phone calls were the most common mode of communication, accounting for 88% of incoming contacts and 85% of outgoing contacts. Emails were the next most common; 9% and 8% respectively (refer to enclosure 6).

- Adherence was the most common reason for contacts being made, accounting for 20% of incoming contacts and 21% of outgoing contacts (refer to enclosure 5).

Demonstration Evaluation

The HIV/AIDS Project is fully operational. Analysis of quality and cost data is continually underway. Enrollment is ongoing with 760 members included in the demonstration project at the end of the fourth quarter of the twelfth year. Reports to CMS have been provided as specified in the Special Terms and Conditions.

Enclosures/Attachments

Attachment A: Outreach

Financial

Enclosure 1: Budget Neutrality Assessment
Enclosure 2: Overall Service Costs by Demonstration Year
Enclosure 3: Actual Participation by Demonstration Quarter
Enclosure 4: ADAP Funds Spent on MaineCare Clients

Communications

Enclosure 5: Contact Tracking by Reason

Enclosure 6: Contact Tracking by Method Used

State Contact

Emily Bean, Program Manager

Office of MaineCare Services

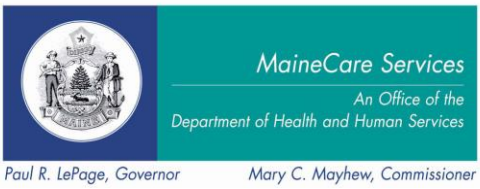
11 State House Station, Augusta, ME 04330

emily.bean@maine.gov

207-624-4005

Date submitted to CMS: February 27, 2015

Attachment A: Outreach



Department of Health and Human Services
MaineCare Services
Nurse Coordinator
11 State House Station
Augusta, Maine 04333-0011
Tel.: (207) 624-4008; Fax: (207) 287-1864
Toll Free (866) 796-2463; TTY Users: Dial 711 (Maine Relay)

November 21, 2014

Dear MaineCare Provider:

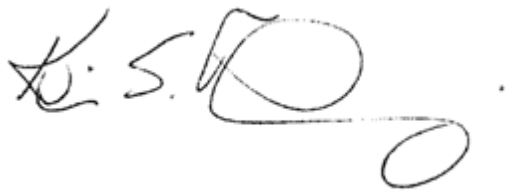
You are receiving this informational letter because you have been identified as a provider for one or more MaineCare members living with HIV. The Department of Health and Human Services has developed quality initiatives to improve care for these MaineCare members. One of these quality initiatives is to provide timely, important information to providers on certain aspects of HIV care. The Department finds it important to provide information to you, as a Primary Care Provider (PCP), because not all PCPs who see MaineCare members living with HIV are experienced in the use of anti-retroviral medication.

Enclosed, please find information from the FDA regarding HIV medication changes and alerts. For more information, please refer to the FDA's website.

Please contact Sherry Boochko, RN at 207-624-4008 if you currently have no patients with HIV.

If you have any questions, you may contact me by sending an email to kevin.flanigan@maine.gov or the Nurse Coordinator, Sherry Boochko, RN at sherry.boochko@maine.gov.

Sincerely,



Kevin Flanigan, MD
Medical Director
MaineCare Services
11 State House Station
Augusta, ME 04333-0011

On September 24, 2014, FDA approved Tybost (cobicistat) 150 mg tablets. Tybost is a CYP3A inhibitor indicated to increase systemic exposure of atazanavir or darunavir (once daily dosing regimen) in combination with other antiretroviral agents in the treatment of HIV-1 infection. The recommended dosages of Tybost and atazanavir or darunavir given with food are presented below.

Recommended Dosing Regimens

Tybost Dosage	Coadministered Agent Dosage	Patient Populations
150 mg orally once daily	atazanavir 300 mg orally once daily	Treatment-naïve or experienced
	darunavir 800 mg orally once daily	Treatment-naïve Treatment-experienced with no darunavir resistance associated substitutions

The data to support the use of atazanavir and Tybost were from a phase 2 and 3 trial in treatment-naïve adults comparing atazanavir/cobicistat 300/150 mg and atazanavir/ritonavir 300/100 mg once daily each in combination with Truvada. The atazanavir/cobicistat based regimen was non-inferior to the atazanavir/ritonavir based regimen. The data to support the use of cobicistat with darunavir is from a multiple dose trial in healthy subjects comparing the relative bioavailability of darunavir/cobicistat 800/150 mg to darunavir/ritonavir 800/100 mg.

The most common adverse drug reactions observed with Tybost in combination with atazanavir (incidence greater than 10%, all Grades) are jaundice, ocular icterus, and nausea.

The following limitations of use were included section 1 *Indications and Usage*:

- Tybost is **not** interchangeable with ritonavir to increase systemic exposure of darunavir 600 mg twice daily, fosamprenavir, saquinavir, or tipranavir due to lack of exposure data. The use of Tybost is not recommended with darunavir 600 mg twice daily, fosamprenavir, saquinavir or tipranavir.
- Complex or unknown mechanisms of drug interactions preclude extrapolation of ritonavir drug interactions to certain Tybost interactions. Tybost and ritonavir when administered with either atazanavir or darunavir may result in different drug interactions when used with concomitant medications.

Prior to starting Tybost, assess estimated creatinine clearance because Tybost decreases estimated creatinine clearance due to inhibition of tubular secretion of creatinine without affecting actual renal glomerular function. When coadministering Tybost with tenofovir disoproxil fumarate (tenofovir DF) assess estimated creatinine clearance, urine glucose, and urine protein at baseline.

Tybost coadministered with tenofovir DF is not recommended in patients who have an estimated creatinine clearance below 70 mL/min because dose adjustment of tenofovir DF is required below 50 mL/min and such dose adjustments have not been established for coadministration with Tybost.

A summary of the *Warnings and Precautions* follows.

- Effects on Serum Creatinine: Assess creatinine clearance (CLcr) before initiating treatment.
- New onset or worsening renal impairment when used with tenofovir disoproxil fumarate: When Tybost is used in combination with a tenofovir disoproxil

fumarate (tenofovir DF) containing regimen, cases of acute renal failure and Fanconi syndrome have been reported. (5.2)

- Use with tenofovir DF: Assess urine glucose and urine protein at baseline and monitor CLcr, urine glucose, and urine protein. Monitor serum phosphorus in patients with or at risk for renal impairment. (5.2)

Labeling for Tybost will be posted soon at Drugs@FDA.

Tybost is a product of Gilead Sciences, Foster City, CA.

Richard Klein
Office of Health and Constituent Affairs
Food and Drug Administration

Kimberly Struble
Division of Antiviral Products
Food and Drug Administration

Steve Morin
Office of Health and Constituent Affairs
Food and Drug Administration

On September 24, 2014, FDA approved Vitekta (elvitegravir) 85 mg and 150 mg tablets. Vitekta is a human immunodeficiency virus type 1 (HIV-1) integrase strand transfer inhibitor indicated in combination with an HIV protease inhibitor coadministered with ritonavir and with other antiretroviral drug(s) for the treatment of HIV-1 infection in antiretroviral treatment-experienced adults.

Dosing and Administration

Vitekta must be administered once daily with food in combination with a protease inhibitor coadministered with ritonavir and another antiretroviral drug. The protease inhibitor and ritonavir dosing regimens presented in the Table 1 below are the recommended regimens for use with Vitekta. For additional dosing instructions for these protease inhibitors and other concomitant antiretroviral drugs, refer to their respective prescribing information.

Table 1 Recommended Regimens*

Dosage of Vitekta	Dosage of Concomitant Protease Inhibitor	Dosage of Concomitant Ritonavir
85 mg orally once daily	Atazanavir 300 mg orally once daily	100 mg orally once daily
	Lopinavir 400 mg orally twice daily	100 mg orally twice daily
150 mg orally once daily	Darunavir 600 mg orally twice daily	100 mg orally twice daily
	Fosamprenavir 700 mg mg orally twice daily	100 mg orally twice daily
	Tipranavir 500 mg orally twice daily	200 mg orally twice daily

*Vitekta in combination with a protease inhibitor and ritonavir must be coadministered with another antiretroviral drug.

No dose adjustment of Vitekta is required for patients with renal impairment.
No dose adjustment of Vitekta is required in patients with mild (Child-Pugh Class A) or moderate hepatic impairment. Vitekta has not been studied in patients with severe hepatic impairment (Child-Pugh Class C). Therefore, Vitekta is not recommended for use in patients with severe hepatic impairment

Based on drug interaction studies conducted with elvitegravir, no clinically significant drug interactions have been either observed or expected when elvitegravir is combined with the following drugs: abacavir, darunavir, emtricitabine, etravirine, fosamprenavir, maraviroc, stavudine, tipranavir, tenofovir disoproxil fumarate, zidovudine; H2-receptor antagonists such as famotidine; proton-pump inhibitors such as omeprazole; and the HMG-CoA reductase inhibitors atorvastatin, pravastatin, and rosuvastatin.

Labeling for Vitekta will be posted soon at Drugs@FDA.

Vitekta is a product of Gilead Sciences, Foster City, CA.

Richard Klein
Office of Health and Constituent Affairs
Food and Drug Administration

Kimberly Struble
Division of Antiviral Products
Food and Drug Administration

Steve Morin
Office of Health and Constituent Affairs
Food and Drug Administration

Department of Health and Human Services
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Authorization to Release Information

We are committed to the privacy of your health information. Please read this form carefully.

☒ Office of Maine Care Services	❒ Substance Abuse and Mental Health Services
❒ Office for Family Independence	❒ Office of Child and Family Services
❒ Maine Centers for Disease Control and Prevention	❒ Office of Aging and Disability Services
❒ Dorothea Dix Psychiatric Center	❒ Other:
❒ Riverview Psychiatric Center	

Your Name:	Your Date of Birth: Your Social Security Number:

Your Address:

Street Town/City State Zip Code

Records to be released, including written, electronic and verbal communication:

☒ All Healthcare, including treatment, services, supplies and medicines

☒ Billing, payment, income, banking, tax, asset, and/or other information regarding financial eligibility for DHHS program benefits such as MaineCare

❒Other:_____

❒ Limit to the following date(s) or type(s) of information:
(e.g. "lab test dated June 2, 2013" or "hospital records from 1/1/12- 1/15/12")

I authorize the DHHS office(s) checked above to:
☒ Release my information to: ☒Obtain my information from:

Ryan White or named Case Management Agency: _____

Address:

_____

Street Town/City State Zip Code

Infectious Disease Specialist:_____

Address:

_____

Street Town/City State Zip Code

If requesting that electronic information be transmitted by email, please clearly print the email address bel

_____

☒ I understand that DHHS systems may not be able to send my information securely through email. I understand that email and the internet have risks that DHHS cannot control and that the information poter could be read by a third party. I accept those risks and still request that DHHS send my information by em Initials _____

Please allow the office(s) named above to disclose my information for the following purpose(s):

❒ Legal ☒Insurance ☒Coordination of Care ❒ Personal Request ❒ Other:

By initialing below, I wish for my release to include the following types of records:

_____ **Mental health treatment provider or program**
(initials)

_____ **Substance/Alcohol/drug abuse treatment provider or program**
(initials)

_____ **HIV infection status or test results:** Maine law requires us to tell you that releasing this information
(initials) may have implications. Positive implications may include giving you more complete care, and negative implications may include discrimination if the data is misused. **DHHS will protect your HIV data, and all your records, as the law requires.**

I (individual/personal representative of individual named above,) give permission to the DHHS office(s) listed above to release and/or share my records as written on this form. This form will remain in effect for one year from the date below. Other releases of my information are permitted during that time unless I revoke this form.

I further understand and agree that:

- DHHS will not condition my treatment, payment for services, or benefits on whether I sign this form, unless I need to sign this form so that the right offices of DHHS can make eligibility or enrollment decisions.

- I have the right to make a written request to access and copy my healthcare or billing information, and a copy fee will be charged as permitted by law.

- If I want a review of my mental health program or provider records before they are released, I can check here. ❒ I understand that the review will be supervised.

- I may take back my permission to share the records listed on this form at any time by contacting the Privacy Officer of the specific DHHS office: Beth Glidden 207-624-6913

- I understand that taking back my permission does not apply to the information that was already shared, as a result of my signing this form. If I revoke my permission, it may be the basis for denial of health benefits or other insurance coverage.

- I may refuse to disclose all or some health care information, but that refusal may result in improper diagnosis or treatment, denial of coverage or a claim for health benefits or other insurance, or other adverse consequences.

- DHHS offices will keep my information confidential as required by law. If I give my permission to share my records with people who are not required by law to keep them private, they may no longer be protected by confidentiality laws.

- If alcohol or drug provider or program records are included in this release, DHHS will tell the person receiving the records that they may not be shared with others who are not on this form without my written permission, unless required or permitted by law.

- I am signing this form voluntarily, and I have the right to a signed copy of this form if I request one.

Date: _____ Signature_____

Personal Representative's authority to sign: _____