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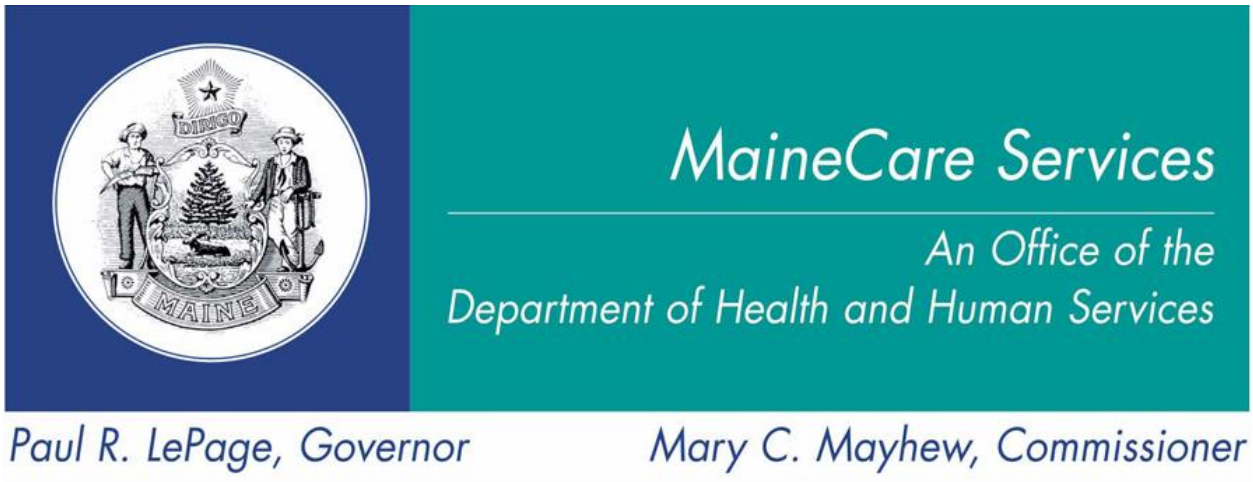

Maine Seal

Quarterly Report

HIV/AIDS 1115 Demonstration Project

SFY 2016 Quarter 1

DY 14 Quarter 1

(1/1/16 -3/31/16)

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

Department of Health and Human Services
MaineCare Services
Nurse Coordinator
11 State House Station
Augusta, Maine 04333-0011
Tel.: (207) 624-4008; Fax: (207) 287-8601
Toll Free (866) 796-2463; TTY Users: Dial 711 (Maine Relay)

Maine Seal

May 26, 2016

Julie Sharp, M.P.P.
Division of State Demonstrations and Waivers
Center for Medicaid and CHIP Services, CMS
Mail Stop S2-01-26
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Ms. Sharp,

Please find enclosed, the quarterly report for the Maine HIV/AIDS Section 1115 Demonstration Waiver for the quarter ending 3/31/2016. Please contact Emily Bean at (207) 624-4005 if further information is needed.

Sincerely,

[redacted]

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

cc: Beth Ketch, Director of Policy and Provider Services
Aimee Campbell-O'Connor, CMS/CMCHO
Sheena Bunnell, PhD

Maine HIV/AIDS Demonstration

Section 1115 Quarterly Report

Demonstration Year: 14 (01/01/2016 - 12/31/2016)

Demonstration Quarter: 1 (01/01/2016 - 03/31/2016)

Maine Fiscal Quarter: 3/2016 (10/01/2015 - 12/31/2015)

Federal Fiscal Year (FFY) 16: 10/01/15 – 09/30/16

Introduction

The MaineCare HIV/AIDS 1115 Demonstration project has completed the first quarter of its fourteenth year. This demonstration was implemented on July 1, 2002 and has been approved through December 31, 2016. The demonstration's goal 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 first quarter of the fourteenth year, there were 805 MaineCare and demonstration members enrolled in the demonstration project.

Enrollment Counts

There were 510 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 333 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 who Changed FPL	Members who Switched Rate Codes	Count of members enrolled at End of Quarter
Enrollees at or below 100% FPL - Demonstration Enrollees	179	188	N/A	9	0	(0)	179
Enrollees above 100% FPL - Demonstration Enrollees	285	304	0	12	10	0	282
Members HIV Positive and MaineCare Eligible	314	333	N/A	17	N/A	(0)	316
Totals	778	825	0	(38)	(10)	(0)	777

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 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 an FDA medication alert to primary care providers regarding Invirase. Alerts are sent via mail or email depending on provider preference (see Attachment A: Outreach). Alerts were sent to approximately 275 providers.

- 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).

- Nurse Coordinator and Program Manager viewing a Webinar: “Meet Your Community Allies: Community Action Agencies & Area Agencies on Aging.”

- Nurse Coordinator and Program Manager meeting with case managers at DEAN/Bangor location.

- Nurse Coordinator and Program Manager meeting with two new case managers from the Frannie Peabody Center (FPC) to provide a MaineCare overview and provide a training manual.

- Program Manager presenting information about the Special Benefit Waiver at training for the staff and Medicare volunteers at the Southern Maine Agency on Aging. Other presenters included the Maine AIDS Drug Assistance Program, Policy Specialists from the Office for Family Independence, and the Maine Bureau of Insurance.

- Sending the 2015 provider survey to 292 providers.

- Sending the 2015 member survey in collaboration with CDC to 759 members.

- Sending the semi-annual clinical data collection letters to 24 providers. This mailing goes to the providers with patients for whom we need CD4 and viral load data (because we were unable to get recent results through CDC).

- Sending the second provider survey mailing to providers who hadn't responded to the first mailing. This mailing went to 228 providers.

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. 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

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.

Member Month Reporting

Eligibility Group by Month	January2016	February2016	March2016	Total for Quarter Ending 3/2016
Enrollees	464	467	461	1,392
Members	314	323	316	953

Eligibility Group by Disease Stage	1 - ASX (asymptomatic)	2 - SX (symptomatic)	3 – AIDS	Total for Quarter Ending 3/16
Enrollees	944	368	80	1,392
Members	554	307	92	953

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 also no complaints received directly by the MaineCare Nurse Coordinator.

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 ED 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 337 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 93 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 1,836 contacts were made in this quarter. Phone calls were the most common mode of communication, accounting for 88% of incoming contacts and 82% of outgoing contacts. Emails were the next most common; 10% and 13%, respectively (refer to enclosure 6).

- Adherence was the most common reason for contacts being made, accounting for 12% 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 777 members included in the demonstration project at the end of the first quarter of the fourteenth 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: May 26, 2016

Attachment A: Outreach

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

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)

January 29, 2016

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 beth.ketch@maine.gov or the Nurse Coordinator, Sherry Boochko, RN at sherry.boochko@maine.gov.

Sincerely,

[redacted]

Beth Ketch, Director
Policy and Provider Services
Office of MaineCare Services

The FDA approved changes to the Invirase (saquinavir mesylate) label to provide updated for drugs that are contraindicated or interact with Invirase/ritonavir.
Also a warning was added to state cobicistat is not recommended for concomitant use with Invirase. The specific changes are summarized below.

Section 2: DOSAGE AND ADMINISTRATION was updated as follows:

Cobicistat is not interchangeable with ritonavir to increase systemic exposure of saquinavir.

For patients already taking ritonavir 100 mg twice daily as part of their antiretroviral regimen, no additional ritonavir is needed.

Section 4: CONTRAINDICATIONS was updated to contraindicate the following agents.

Drugs That Are Contraindicated with INVIRASE/ritonavir

Drug Class	**Drugs Within Class That Are Contraindicated With INVIRASE/ritonavir**	**Clinical Comment**
Anti-infectives	Clarithromycin, erythromycin, halofantrine, pentamidine	Potential for serious and/or life-threatening cardiac arrhythmia.
HIV-1 Protease Inhibitor	Atazanavir	Potential for serious and/or life-threatening cardiac arrhythmia.
Immunosuppressant	Tacrolimus	Potential for serious and/or life-threatening cardiac arrhythmia.
Neuroleptics	Pimozide	Potential for serious and/or life threatening reactions such as cardiac arrhythmias.

	Chlorpromazine Sertindole Clozapine Haloperidol Mesoridazine Phenothiazines Thioridazine Ziprasidone	
Other drugs that are CYP3A substrates	Dapsone Disopyramide Quinine	Potential for serious and/or life-threatening cardiac arrhythmia.

The following statement was added to section 5: WARNINGS and PRECAUTIONS.
INVIRASE is not recommended for use in combination with cobicistat.
Dosing recommendations for this combination have not been established. Cobicistat is also not recommended in combination with regimens containing ritonavir due to similar effects of cobicistat and ritonavir on CYP3A. Please refer to the cobicistat full prescribing information for additional precautionary measures.

Please refer to section 7 for a Drug Interaction list.

7.4 Drugs without Clinically Significant Interactions with INVIRASE/ritonavir

Based on drug interaction studies conducted with INVIRASE/ritonavir, no clinically significant effect was observed for saquinavir when coadministered with fosamprenavir. No clinically significant effect was observed for enfuvirtide when coadministered with INVIRASE/ritonavir.

Section 12: Clinical Pharmacology was updated to include the following statement

The HIV-1 antiviral drugs didanosine, tenofovir, and zidovudine are not predicted to have any clinically significant effect on the pharmacokinetics of saquinavir with and without ritonavir. No clinically significant effect on the pharmacokinetic parameters of enfuvirtide was observed with coadministration of INVIRASE/ritonavir. No clinically significant effect on the pharmacokinetic parameters of saquinavir was observed with coadministration of fosamprenavir.

The complete product label is available on the FDAs website.

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
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)

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 be

_____

☒ 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 en 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: _____

Budget Neutrality Assessment

(This page automatically calculates entered data.)

	Annual Assessment														
	DY - 1 FFY: 10/01/02 - 9/30/03	**DY - 2 FFY: 10/01/03 - 9/30/04**	**DY - 3 FFY: 10/01/04 - 9/30/05**	**DY - 4 FFY: 10/01/05 - 9/30/06**	**DY - 5 FFY: 10/01/06 - 9/30/07**	**DY - 6 FFY: 10/01/07 - 9/30/08**	**DY - 7 FFY: 10/01/08 - 9/30/09**	**DY - 8 FFY: 10/01/09 - 9/30/10**	**DY - 9 FFY: 10/01/10 - 9/30/11**	**DY - 10 FFY: 10/01/11 - 9/30/12**	**DY - 11 FFY: 10/01/12 - 9/30/13**	**DY - 12 FFY: 10/01/13 - 9/30/14**	**DY - 13 FFY: 10/1/14 - 09/30/15**	**DY - 14 FFY: 10/1/15 - 09/30/16**	**Total Computable Ceiling**
Cumulative Expenditure Targets	$8,706,056.00	$18,949,248.00	$30,707,947.00	$43,937,686.00	$58,571,556.00	$67,382,817.00	$78,965,794.00	$93,255,027.00	$104,436,521.00	$118,909,175.00	$141,146,776.00	$154,141,747.00	$154,141,747.00	$154,141,747.00	$1,227,393,844.00
Population Group(s) (as identified in MBES From CMS 64 Waiver Expenditure Report Schedule C Summary) **Total Demo & Medicaid Costs**	$5,082,618.00	$7,737,499.00	$6,625,681.00	$5,139,905.00	$7,816,713.00	$8,068,145.00	$7,630,086.00	$5,531,591.00	$7,509,122.00	$7,693,950.00	$7,834,029.00	$8,251,720.00	$8,881,619.00	$1,715,153.00	$95,517,831.00
Costs Over/Under Target	-$3,623,438.00	-$6,129,131.00	-$11,262,149.00	-$19,351,983.00	-$26,169,140.00	-$26,912,256.00	-$30,865,147.00	-$39,622,789.00	-$43,295,161.00	-$50,073,865.00	-$64,477,437.00	-$69,220,688.00	-$60,339,069.00	-$58,623,916.00	-$1,131,876,013.00

Note - FFY15 Q3 (Waiver DY 12 2014): Updated the "Annual Expenditure Targets" with the figures provided in an email from CMS forwarded by Emily Bean on 5/20/2015.

Date: 5/10/2016