REPORT TO THE TWENTY-SIXTH HAWAII STATE LEGISLATURE 2012

IN ACCORDANCE WITH THE PROVISIONS OF ACT 92, SESSION LAWS OF HAWAII 2007, ON IMMUNOSUPPRESSANT MEDICATION

DEPARTMENT OF HUMAN SERVICES
MED-QUEST DIVISION
December 2011

ECONOMIC ASSESSMENT IMPACT REPORT ON IMMUNOSUPPRESSANT MEDICATION FOR QUEST PROGRAM CLIENTS AS REQUIRED BY ACT 92, SESSION LAWS OF HAWAII (SLH) 2007

Act 241, SLH 2005, created chapter 346, Part XVI Medicaid Preauthorization Exemption, Hawaii Revised Statutes (HRS), to allow any physician licensed in this State who treats a Medicaid recipient who is suffering from the human immunodeficiency virus (HIV), acquired immune deficiency syndrome (AIDS), or Hepatitis C, or who is in need of transplant immunosuppressives, to prescribe any medications approved by the United States Food and Drug Administration and eligible for Omnibus Budget Reconciliation Rebates Act (OBRA) that are necessary to treat the condition, without having to comply with the requirements of any preauthorization procedure established by any other provision of chapter 346. The preauthorization exemption was not applied to patients in QUEST health plans. Act 241 was codified as sections 346-351 and 346-352, HRS.

Act 92, SLH 2007, amended section 346-352, HRS, to provide equal access for Medicaid clients by deleting the exclusion of patients in QUEST health plans from the preauthorization exemption.

Section 3 of Act 92, SLH 2007, requires an economic impact assessment report to the Legislature to include information obtained from insurance providers, who provide Medicaid and QUEST coverage, on the additional costs incurred as a result of providing access to immunosuppressant and other medications to QUEST patients suffering from the conditions as described in section 346-352, HRS.

Medicaid Fee-For-Service (FFS) Only

HIV/AIDS

Historically, the Medicaid Fee-For-Service (FFS) program had very few restrictions on medications for treating HIV/AIDS. Thus, little impact was noted when comparing the findings of six months prior to implementing Act 241 (01/01/05 to 06/30/05) versus those of six months post implementation of Act 241 (07/01/05 to 12/31/05). Claim count and drug costs increased as the number of utilizers increased. No complaint was received by the Med-QUEST Division (MQD) regarding access for the FFS population prior to or after the implementation of Act 241.

On January 1, 2006, more than 50% of the population in FFS began receiving drug coverage under Medicare Part D as a primary insurance coverage. As a result, Medicaid FFS, the payor of last resort, noted a dramatic decrease in utilization, claim count, and drug costs. A slight increase followed over the next three and a half years until QUEST Expanded Access (QExA) was implemented on February 1, 2009, when 95% of the FFS population were transitioned into the QExA program.

HIV/AIDS

Service Period	Average Per Month		
	Claims Count	Drug Costs	Count of Unique Utilizers
01/01/05 to 06/30/05	578	$298,944	219
07/01/05 to 12/31/05	604	$331,713	230
01/01/06 to 06/30/06	244	$132,406	95
07/01/06 to 06/30/07	243	$162,110	103
07/01/07 to 12/31/07	230	$168,860	105
01/01/08 to 06/30/08*	226	$182,495	109
07/01/08 to 01/31/09	215	$184,878	107
02/01/09 to 06/30/09**	7	$6,073	5
07/01/09 to 06/30/10	6	$5,133	2
07/01/10 to 06/30/11	5	$3,968	4

*Act 92, SLH 2007 implemented.
**QUEST Expanded Access implemented.

Hepatitis C

Medications for Hepatitis C also had few restrictions. As a result, little impact was noted when comparing the findings of six months prior to implementing Act 241 (01/01/05 to 6/30/05) versus those of six months post-implementation of Act 241 (07/01/05 to 12/31/05). Claim count and drug costs increased as the number of utilizers increased. No complaint was received by MQD regarding access for the FFS population prior to or after the implementation of Act 241.

On January 1, 2006, more than 50% of the population in FFS began receiving drug coverage under Medicare Part D as a primary insurance. As a result, Medicaid FFS, the payor of last resort, noted a dramatic decrease in utilization, claim count and drug costs. A slight increase followed over the next three and a half years until QExA was implemented, which decreased the FFS population by approximately 95%.

Hepatitis C

Service Period	Average Per Month		
	Claims Count	Drug Costs	Count of Unique Utilizers
01/01/05 to 06/30/05	40	$50,149	20
07/01/05 to 12/31/05	40	$51,504	21
01/01/06 to 06/30/06	24	$30,257	12
07/01/06 to 06/30/07	21	$29,028	11
07/01/07 to 12/31/07	22	$31,806	10
01/01/08 to 06/30/08*	28	$41,549	13
07/01/08 to 01/31/09	25	$42,444	12
02/01/09 to 06/30/09**	0	$0	0
07/01/09 to 06/30/10	<1	$448	<1
07/01/10 to 06/30/11	1	$1,746	1

*Act 92, SLH 2007 implemented.
**QUEST Expanded Access implemented.

Immunosuppressive Medications for Organ and Tissue Transplants

Immunosuppressive medications for treatment of organ and tissue transplants had few formulary restrictions. Little impact was noted when comparing the findings of six months prior to implementing Act 241 (01/01/05 to 06/30/05) versus those of six months post implementation of Act 241 (07/01/05 to 12/31/05). Claim count and drug costs increased as the number of utilizers increased. No complaint was received by MQD regarding access for the FFS population prior to or after the implementation of Act 241. Some immunosuppressants can be used for various medical conditions besides transplants. Pharmacy claims do not indicate the diagnosis, so all prescriptions are included. Clients who are in the State of Hawaii Organ and Tissue Transplant (SHOTT) program are also included.

On January 1, 2006, more than 50% of the population in FFS began receiving drug coverage under Medicare Part D as a primary insurance. Medicaid FFS, the payor of last resort, therefore noted utilization a dramatic decrease in utilization, claim count and drug costs. A slight increase followed over the next three and a half years until QExA was implemented, which decreased the FFS population by approximately 95%.

Immunosuppressives for Organ and Tissue Transplants (including SHOTT)

Service Period	Average Per Month		
	Claims Count	Drug Costs	Count of Unique Utilizers
01/01/05 to 06/30/05	189	$22,646	111
07/01/05 to 12/31/05	251	$27,842	137
01/01/06 to 06/30/06	127	$21,442	75
07/01/06 to 06/30/07	123	$22,752	72
07/01/07 to 12/31/07	115	$23,114	67
01/01/08 to 06/30/08	117	$20,935	69
07/01/08 to 01/31/09	122	$21,973	69
02/01/09 to 06/30/09*	9	$4,203	6
07/01/09 to 06/30/10	3	$2,349	6
07/01/10 to 06/30/11	19	$6,501	9

*QUEST Expanded Access implemented.

QUEST

The Medicaid QUEST programs are to provide equal access to medications for Medicaid clients who suffer from HIV/AIDS, Hepatitis C, or who need immunosuppressives as a result of organ or tissue transplants, per Act 92 SLH 2007 beginning July 1, 2007.

ALOHACARE

HIV/AIDS

Minimal impact is noticed with this small population when comparing the findings prior to implementing Act 92 (prior to 07/1/07) versus those post implementation of Act 92 (post 01/01/08).

Service Period	Average Per Month		
	Claims Count	Drug Costs	Count of Unique Utilizers
07/01/06 to 06/30/07	43	$28,873	19
07/01/07 to 12/31/07	31	$22,965	14
01/01/08 to 06/30/08	38	$35,367	21
07/01/08 to 01/31/09	32	$30,630	21
02/01/09 to 06/30/09	45	$43,875	29
07/01/09 to 06/30/10	57	$60,400	40
07/01/10 to 06/30/11	67	$70,337	45

Hepatitis C

Minimal impact is noticed with this small population.

Service Period	Average Per Month		
	Claims Count	Drug Costs	Count of Unique Utilizers
07/01/06 to 06/30/07	14	$14,414	9
07/01/07 to 12/31/07	17	$20,584	3
01/01/08 to 06/30/08	17	$23,304	3
07/01/08 to 06/30/09	18	$25,453	2
07/01/09 to 06/30/10	17	$24,314	8
07/01/10 to 06/30/11	20	$29,172	10

Immunosuppressives for Organ and Tissue Transplants

Minimal impact is noticed with this small population.

Service Period	Average Per Month		
	Claims Count	Drug Costs	Count of Unique Utilizers
07/01/06 to 06/30/07	16	$4,630	12
07/01/07 to 12/31/07	14	$3,533	11
01/01/08 to 06/30/08	16	$4,492	10
07/01/08 to 06/30/09	16	$6,292	11
07/01/09 to 06/30/10	12	$3,860	9
07/01/10 to 06/30/11	13	$2,540	11

HMSA

HIV/AIDS

Minimal impact is noticed with this small population when comparing the findings prior to implementing Act 92 (prior to 07/01/07) versus those post implementation of Act 92 (post 01/01/08).

Service Period	Average Per Month		
	Claims Count	Drug Costs	Count of Unique Utilizers
07/01/07 to 12/31/07	82	$60,688	40
01/01/08 to 06/30/08	96	$79,044	47
07/01/08 to 06/30/09	91	$78,558	51
07/01/09 to 06/30/10	125	$110,373	76
07/01/10 to 06/30/11	135	$123,289	125

Hepatitis C

Minimal impact is noticed with this small population when comparing the findings prior to implementing Act 92 (prior to 07/01/07) versus those post implementation of Act 92 (post 01/01/08).

Service Period	Average Per Month		
	Claims Count	Drug Costs	Count of Unique Utilizers
07/01/07 to 12/31/07	22	$26,506	12
01/01/08 to 06/30/08	32	$45,079	17
07/01/08 to 06/30/09	31	$46,257	15
07/01/09 to 06/30/10	18	$27,386	9
07/01/10 to 06/30/11	34	$54,604	32

Immunosuppressives for Organ and Tissue Transplants

Minimal impact is noticed with this small population when comparing the findings prior to implementing Act 92 (prior to 07/01/07) versus those post implementation of Act 92 (post 01/01/08).

Service Period	Average Per Month		
	Claims Count	Drug Costs	Count of Unique Utilizers
07/01/07 to 12/31/07	30	$9,255	23
01/01/08 to 06/30/08	28	$11,324	23
07/01/08 to 06/30/09	27	$11,040	23
07/01/09 to 06/30/10	39	$12,144	30
07/01/10 to 06/30/11	49	$12,152	46

KAISER

HIV/AIDS

Minimal impact is noticed with this small population when comparing the findings prior to implementing Act 92 (prior to 07/01/07) versus those post implementation of Act 92 (post 01/01/08).

Service Period	Average Per Month		
	Claims Count	Drug Costs	Count of Unique Utilizers
07/01/07 to 12/31/07	22	$15,342	11
01/01/08 to 06/30/08	16	$11,137	9
07/01/08 to 06/30/09	22	$16,010	11
07/01/09 to 06/30/10	26	$21,660	14
07/01/10 to 06/30/11	25	$22,969	14

Hepatitis C

Minimal impact is noticed with this small population when comparing the findings prior to implementing Act 92 (prior to 07/01/07) versus those post implementation of Act 92 (post 01/01/08).

Service Period	Average Per Month		
	Claims Count	Drug Costs	Count of Unique Utilizers
07/01/07 to 12/31/07	11	$6,921	6
01/01/08 to 06/30/08	5	$3,198	3
07/01/08 to 06/30/09	5	$3,836	3
07/01/09 to 06/30/10	4	$2,615	2
07/01/10 to 06/30/11	4	$3,617	2

Immunosuppressives for Organ Transplants

Minimal impact is noticed with this small population when comparing the findings prior to implementing Act 92 (prior to 07/01/07) versus those post implementation of Act 92 (post 01/01/08).

Service Period	Average Per Month		
	Claims Count	Drug Costs	Count of Unique Utilizers
07/01/07 to 12/31/07	7	$2,279	5
01/01/08 to 06/30/08	7	$3,017	5
07/01/08 to 06/30/09	9	$1,883	7
07/01/09 to 06/30/10	9	$1,175	7
07/01/10 to 06/30/11	11	$1,559	9

SUMMERLIN

Service to clients began August 1, 2007, and no client requested medications in the categories of HIV, AIDS, Hepatitis C, or transplant-related immunosuppressives. As of July 2009, Summerlin no longer functioned as a QUEST plan.

Service Period	Average Per Month		
	Claims Count	Drug Costs	Count of Unique Utilizers
08/01/07 to 12/31/07	0	$0	0
01/01/08 to 06/30/08	0	$0	0
07/01/08 to 06/30/09	0	$0	0
02/01/09 to 06/30/09	0	$0	0

QUEST Expanded Access (QExA)

QExA was implemented on February 1, 2009, decreasing the FFS population by approximately 95%. Minimal impact is noticed with this small population as the recipients have transitioned from FFS to QExA.

EVERCARE

HIV/AIDS

Service Period	Average Per Month		
	Claims Count	Drug Costs	Count of Unique Utilizers
02/01/09 to 06/30/09	87	$63,086	13
07/01/09 to 06/30/10	97	$70,026	77
07/01/10 to 06/30/11	85	$76,105	26

Hepatitis C

Service Period	Average Per Month		
	Claims Count	Drug Costs	Count of Unique Utilizers
02/01/09 to 06/30/09	13	$19,430	2
07/01/09 to 06/30/10	9	$15,620	1
07/01/10 to 06/30/11	11	$18,504	3

Immunosuppressives for Organ Transplants

Service Period	Average Per Month		
	Claims Count	Drug Costs	Count of Unique Utilizers
02/01/09 to 06/30/09	96	$45,232	46
07/01/09 to 06/30/10	91	$29,929	49
07/01/10 to 06/30/11	81	$13,470	27

OHANA HEALTH PLAN

HIV/AIDS

Service Period	Average Per Month		
	Claims Count	Drug Costs	Count of Unique Utilizers
02/01/09 to 06/30/09	139	$124,349	72
07/01/09 to 06/30/10	134	$125,172	73
07/01/10 to 06/30/11	136	$129,066	73

Hepatitis C

Service Period	Average Per Month		
	Claims Count	Drug Costs	Count of Unique Utilizers
02/01/09 to 06/30/09	9	$14,236	4
07/01/09 to 06/30/10	17	$29,270	8
07/01/10 to 06/30/11	14	$26,916	7

Immunosuppressives as a Result of Organ Transplants

Service Period	Average Per Month		
	Claims Count	Drug Costs	Count of Unique Utilizers
02/01/09 to 06/30/09	151	$95,608	96
07/01/09 to 06/30/10	132	$93,581	88
07/01/10 to 06/30/11	128	$96,654	84

Conclusion

Implementations of Act 241 and Act 92 did not incur additional costs. Regardless of whether a client is in the Medicaid FFS (including QExA plans after February 1, 2009) or the Medicaid QUEST program, medications for Medicaid clients who suffer from HIV/AIDS, Hepatitis C, or who need immunosuppressives for organ or tissue transplants are readily accessible. No complaint was received by MQD regarding access prior to or after the implementation of Act 241 and Act 92.

Increases in drug costs are seen for reasons other than Act 241 and Act 92 and can be due to a number of factors, which include the following:

1) The increase in total number of Medicaid program recipients including those with the conditions covered by this report. June 2005 had 200,300 recipients eligible in Medicaid. This increased 35.8% to 272,200 eligible recipients by June 2011.

2) New drugs with unique mechanisms of action have entered the market since Act 241 and Act 92 were implemented. The cost of new brand drugs far exceeds the

cost of generic drugs; cost-benefit analysis would indicate if the additional cost provides at least proportional additional benefit.

3) Inflation of the cost of the individual drugs themselves, which in some cases doubled within one reporting period.

Revision or reconsideration of the changes to Section 346-352, HRS, made by Act 92, SLH 2007 may need to be examined given the following information:

- New and more expensive medications are not necessarily more effective. However, pharmaceutical manufacturer detailing and other advertising impacts prescribing behavior. Allowing a mechanism to ensure cost-effective prescribing will result in greater value of precious State funds.

- New treatments may become available that are more effective than older treatments but also have adverse effects. Ensuring prescribing is in accordance with evidence-based guidelines and to the appropriate patient populations is important. Inappropriate prescribing such as for indications outside of those approved by the U.S. Food and Drug Administration or for patient populations in which the intervention does not have demonstrated effectiveness may have greater risk of harm than benefit for the patients.

- As previously brand-only drugs go off patent and generic versions of them become available, allowing substitution of a brand medication with an identical ingredient generic (i.e. generic substitution) would help reduce expenditures without negative clinical impact.

- Allowing unrestricted access to certain medications as required by Act 92, SLH 2007, may result in waste and even potentially cause patients harm. Oversight or pre-authorization of prescriptions may be warranted.