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JEREMIAH W. (JAY) NIXON, GOVERNOR • BRIAN KINKADE, DIRECTO

P.O. BOX 1527 • BROADWAY STATE OFFICE BUILDING • JEFFERSON CITY, MO 65102-152
WWW.DSS.MO.GOV • 573-751-4815 • 573-751-3203 FA

February 19, 2015

VIA: email

Manning Pellanda
Director
Division of State Demonstration and Waivers
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Mail Stop S2-26-12
Baltimore, MD 21244

Dear Ms. Mann:

Please see the attached request to amend the Gateway to Better Health Section 1115 demonstration to authorize coverage of brand name insulin and inhalers, which are not available in a generic alternative. As we explain in more detail in the attached request, covering these drugs will help Gateway enrollees manage chronic conditions and avoid preventable emergency department visits and hospitalizations.

This amendment request complies with the requirements in Paragraphs 7 and 14 in the demonstration's Special Terms and Conditions.

Please feel free to contact Joe Parks, M.D. at (573) 751-6884, if you have any questions about this amendment request.

Sincerely,

Brian Kinkade
Director

Attachment

cc: James Scott
Mehreen Hossain

Gateway to Better Health Demonstration

Amendment Request

February 19, 2015

Number: 11-W-00250/7

Background

On July 28, 2010, CMS approved the State of Missouri's "Gateway to Better Health" Demonstration, which preserved access to ambulatory care for low-income, uninsured individuals in St. Louis City and County. The Demonstration was amended in June 2012 to enable the Safety Net Pilot Program to be implemented by July 1, 2012. The July 1, 2012, implementation of the Pilot Program ensured patients of the St. Louis safety net maintained access to primary care and specialty care. CMS approved a one-year extension of the Demonstration on September 27, 2013, and again on July 16, 2014. The Demonstration is currently scheduled to expire on December 31, 2015. The State has been authorized to spend up to $30 million (total computable) annually to preserve and improve primary care and specialty care in St. Louis in lieu of spending that amount of statutorily authorized funding on payments to disproportionate share hospitals (DSHs). The Demonstration includes the following main objectives:

I. Preserve the St. Louis City and St. Louis County safety net of health care services available to the uninsured until a transition to health care coverage is available under the Affordable Care Act (ACA);

II. Connect the uninsured and Medicaid populations to a primary care home which will enhance coordination, quality, and efficiency of health care through patient and provider involvement;

III. Maintain and enhance quality service delivery strategies to reduce health disparities;

IV. Have the affiliation partners provide health care services to an additional 2 percent of uninsured individuals over the current service levels by July 1, 2012; and

V. Transition the affiliation partner community to a coverage model, as opposed to a direct payment model, by July 1, 2012.

For the first two years of the Demonstration, through June 30, 2012 certain providers referred to as Affiliation Partners were paid directly for uncompensated care. These providers included St. Louis ConnectCare, Grace Hill Health Centers, and Myrtle Hilliard Davis Comprehensive Health Centers.

The program transitioned to a coverage model pilot on July 1, 2012. The goal of the Gateway to Better Health Pilot Program is to provide a bridge for safety net providers and their uninsured patients in St. Louis City and St. Louis County to coverage options available through federal health care reform.

From July 1, 2012, to December 31, 2013, the Pilot Program provided primary, urgent, and specialty care coverage to uninsured[1] adults in St. Louis City and St. Louis County, aged 19-64, who were below 133% of the Federal Poverty Level (FPL), as well as specialty care coverage only to the same population up to 200% of the FPL. The Demonstration was scheduled to expire December 31, 2014.

The Missouri legislature did not expand Medicaid eligibility during its 2013 or 2014 legislative session. On September 27, 2013, and again on July 16, 2014, CMS approved a one-year extension of the Gateway Demonstration program for patients up to 100% FPL, or until Missouri's Medicaid eligibility is expanded to include the waiver population.

[1] To be considered to be "uninsured" applicants must not be eligible for coverage through the Medicaid State Plan. Screening for Medicaid eligibility is the first step of the Gateway to Better Health eligibility determination.

Historical Background

The current funding provided by this Demonstration Project (Number: 11-W-00250/7) builds on and maintains the success of the "St. Louis Model," which was first implemented through the "Health Care for the Indigent of St. Louis" amendment to the Medicaid Section 1115 Demonstration Project (Number: 11-W00122/7). This amendment authorized the diversion of 6.27 percent of the Statewide DSH cash distributions, previously allocated to St. Louis Regional Hospital, to a "St. Louis Safety Net Funding Pool," which funded primary and specialty care for the uninsured. The downsizing and ultimate closure of St. Louis Regional Hospital in 1997 led to the "St. Louis Model." Under this model, the DSH funds were distributed directly to the legacy clinics of St. Louis Regional Hospital, which were operated by St. Louis ConnectCare, Grace Hill Health Centers and Myrtle Hilliard Davis Comprehensive Health Centers. The funds were distributed directly to these organizations through June 30, 2012. This funding converted to a "coverage model" per the conditions of the Demonstration.

The SLRHC was established under this prior waiver to coordinate, monitor, and report on the safety net network's activities and to make recommendations as to the allocation of these funds. Today, the SLRHC is charged with improving health care access and delivery to the uninsured and underinsured in the St. Louis region, and is the fiscal agent for this Demonstration.

The Commission works within a large network that includes St. Louis County and its public health department, area Federally Qualified Health Centers (FQHCs), the St. Louis City health department, and area hospitals and medical schools.

Amendment Description

This amendment proposes to add certain brand name pharmaceuticals that do not have generic alternatives to the Demonstration's benefits package. Currently, the Demonstration covers generic prescriptions available from community health centers. Specifically, the drugs added under this amendment would be insulin and inhalers that are not available in a generic alternative. All pharmaceuticals covered by the Demonstration, including the insulin and inhalers, would continue to be dispensed by patients' primary care homes and covered in the alternative payment used to reimburse community health centers for medical and dental services and pharmaceuticals.

After consulting with providers and patients, it was determined that covering these drugs would reduce barriers for patients in accessing these interventions, which are critical to managing chronic conditions and to reducing preventable emergency department visits and hospitalizations. Throughout the Demonstration, patients have accessed brand name drugs through their health centers' sliding fee scales and through Prescription Assistance Programs (PAPs) available through pharmaceutical manufacturers. Recently, patients began experiencing more administrative barriers in accessing free or low-cost drugs through PAPs. By covering these drugs, patients will be able to receive them at their health center without any further administrative requirement and at a lower cost than the sliding fee scale.

Furthermore, these two pharmaceutical interventions are directly related to the Demonstration's evaluation and incentive measures, which are designed to improve the health of those patients living with chronic disease.

The objective of this amendment would be to improve the health outcomes of those patients living with chronic conditions as measured by the metrics outlined in the Demonstration's Evaluation Design.

This amendment request is being made after significant consultation with the program's providers, who indicated that these two drug classes are the ones most often prescribed that do not have generic alternatives. Actuarial analysis showed that a full brand name drug benefit was cost prohibitive for the Demonstration without significantly lowering the enrollment cap.

The specific drugs to be dispensed include but are not limited to:

HUMALOG	Insulin
HUMALOG KWIKPEN	Insulin
HUMALOG MIX 75/25	Insulin
HUMULIN 70/30	Insulin
HUMULIN 70/30 PEN	Insulin
HUMULIN N	Insulin
HUMULIN N U-100 PEN	Insulin
HUMULIN R	Insulin
LANTUS	Insulin
LANTUSSOLOSTAR	Insulin
LEVEMIR	Insulin
NOVOLIN 70/30	Insulin
NOVOLIN N	Insulin

NOVOLIN R	Insulin
NOVOLOG	Insulin
NOVOLOG FLEXPEN	Insulin
NOVOLOG MIX 70/30	Insulin
NOVOLOG MIX 70/30 PREFILL	Insulin
ASMANEX 120 METERED DOSES	Steroid Inhalants
FLOVENT HFA	Steroid Inhalants
PULMICORT	Steroid Inhalants
PULMICORT FLEXHALER	Steroid Inhalants
QVAR	Steroid Inhalants

Financial Analysis of the Amendment

With an anticipated implementation date of May 1, 2015, the five community health centers in the Gateway to Better Health network will receive an estimated additional $2.24 per member per month to cover the cost of these two drug classes. This rate will be certified by the program's actuaries, Wakely Consulting Group, for the remainder of calendar year 2015. New rates will be set for calendar year 2016 if the Missouri legislature does not approve Medicaid expansion for 2016 and CMS approves an extension of the Demonstration into 2016.

With this additional cost, the enrollment cap for the program will be lowered to approximately 21,432 from 22,600, effective May 1, 2015. As of November 18, 2014, program enrollment was 21,044 – below the proposed enrollment cap after the implementation of the new benefits.

The program will remain budget neutral with the implementation of this amendment. See Appendix I for a complete analysis of budget neutrality with the amendment and without the amendment.

Public Input

The request for this amendment is a result of the public process by which the St. Louis Regional Health Commission (SLRHC) manages the Demonstration in partnership with the State of Missouri. The SLRHC's Community and Provider Services Advisory Boards had requested that the program monitor the ability of patients' to access these important medications. With the program's current enrollment and the increasing administrative requirements of the PAPs, the Gateway Pilot Program Planning Team, which includes providers and community members, recommended that insulin and inhalers be covered in order to continue to provide high-quality, low-cost care to uninsured, low-income individuals, especially those living with chronic conditions.

The State and the SLRHC solicited input from the public about this proposed amendment in compliance with paragraphs 7 and 14 of the Demonstration's Special Terms and Conditions. The board of the SLRHC approved this recommendation at its public meeting on November 19, 2014. In addition, a draft of the amendment request was made available for public inspection and was reviewed by the SLRHC's Provider Services Advisory Board at a public meeting on December 2, 2014, as well as at a public meeting on

December 3, 2014. At these two public meetings, the amendment was on the agenda and members of the community were invited to comment on the proposal. These meetings were publicized on the SLRHC's web site, as well as in newspapers throughout the State, as part of the public notice process for an extension request of the Demonstration.

In these meetings, parties were supportive of the proposed amendment with no dissenting opinion expressed. Approximately 30 attendees of the Provider Services Advisory Board, including physicians, supported the request, indicating that these two drug classes were the most important to cover. The 50 people at the December 3 meeting also unanimously supported the recommendation. A representative from the St. Louis Diabetes Coalition submitted verbal comments supporting the recommendation, explaining that lowering barriers to accessing insulin will increase compliance with physician's recommendations. Two participants submitted written comments about the amendment request:

> "As long as the state of Missouri resists Medicaid expansion, and as long as the wait times for Medicaid approval drag on for 3, 6, 9, or 12 months, Gateway to Better Health is absolutely essential to the health of St. Louis. Without Gateway, thousands of people would be without access to the care that they need. Moreover, without the addition of coverage for insulin and inhalers many of those patients already benefitting from Gateway will face suboptimal health outcomes."

> "I love that the program is looking to add insulin and inhalers to the covered benefits. As a diabetes educator and diabetic, I know firsthand that patients often go without taking their medications because they are unaffordable. The addition of these drugs will really help to improve the health of Gateway patients."

Impact to Evaluation Design

The current Evaluation Design requires tracking a number of quality measures that could be impacted by the implementation of this amendment. These measures are detailed below.

<u>Pay-for-Performance Measures Reported Every Six Months</u>

Patients with Diabetes, Hypertension, CHF or COPD

Minimum of at least 2 office visits within 1 year (6 months before/after reporting period start date)

Patients with Diabetes

Have one HgbA1c test 6 months after reporting period start date

Patients with Diabetes

Have a HgbA1c less than or equal to 9% on most recent HgbA1c test within the reporting period

<u>Quality Measures Reported Annually</u>

Diabetes: HbA1c Control

Proportion of adult patients 18 to 75 years of age with a diagnosis of Type I or Type II diabetes whose hemoglobin A1c (HbA1c) was less than 9% at the time of the last reading in the measurement year. Results are reported in four categories: less than 7%; greater than or equal to 7% and less than 8%; greater than or equal to 8% and less than or equal to 9%; and greater than 9%

No additional changes to the Evaluation Design are recommended.

Appendix I: Budget Neutrality Analysis

Budget Neutrality Without Amendment: *Budget neutrality projections are through the end of calendar year 2016, in order to reflect the extension request to be submitted by the State at the end of 2014 in the event the Missouri legislature does not approve Medicaid expansion during its 2015 session.*

Budget Neutrality

Gateway to Better Health (Total Computable)

	DY 1 FFY 2010 07/28/2010 - 09/30/2010	DY 2 FFY 2011 10/01/2010 - 09/30/2011	DY 3 FFY 2012 10/01/2011- 9/30/2012	DY 4 FFY 2013 10/01/2012- 09/30/2013	DY 5 FFY 2014 10/01/2013- 9/30/2014	DY 6 FFY 2015 10/01/2014- 09/30/2015	DY 7 FFY 2016 10/01/2015- 09/30/2016	DY 8 FFY 2017 10/01/2016- 12/31/2016	Total - 6.5 year demonstration 07/28/2010 to 12/31/2015
No. of months in DY	3 months	12 months	12 months	12 months	12 months	12 months	12 months	3 months	
No. of months of direct payments to facilities	3 months	12 months	9 months	0 months	0 months	0 months	0 months	0 months	
No. of months of Pilot Program (will be implemented on 07/01/2012)	0 months	0 months	3 months	12 months	12 months	12 months	12 months	3 months	
Without Waiver Projections									
Estimated DSH Allotment**	$189,681,265	$748,599,611	*$764,632,976*	*$764,632,976*	$764,632,976	*$764,632,976*	*$726,401,327*	*$172,520,315*	**$4,895,734,422**
Without Waiver Total	**$189,681,265**	**$748,599,611**	**$764,632,976**	**$764,632,976**	**$764,632,976**	**$764,632,976**	**$726,401,327**	**$172,520,315**	**$4,895,734,422**
With Waiver Projections									
Residual DSH	$175,037,571	$679,083,062	*$738,644,994*	*$735,638,937*	*$738,258,382*	*$734,979,290*	*$700,120,105*	*$166,185,176*	$4,667,947,516
St. Louis ConnectCare	$4,850,000	$18,150,000	$14,879,909	*$3,148,648*	$118,489	$0	$0	$0	$41,147,045
Grace Hill Neighborhood Health Centers	$1,462,500	$5,850,000	*$5,071,706*	*$5,016,507*	*$6,073,656*	*$6,599,993*	*$6,375,368*	*$1,527,148*	$37,976,878
Myrtle Davis Comprehensive Health Centers	$937,500	$3,750,000	*$3,097,841*	*$2,108,161*	*$1,838,040*	*$2,439,128*	*$2,356,112*	*$564,381*	$17,091,163
Contingency Provider Network	$0	$0	*$379,372*	*$4,254,902*	*$5,469,199*	*$5,658,112*	*$5,474,290*	*$1,311,306*	$22,547,181
Voucher	$0	$0	$0	*$4,541,262*	*$6,358,786*	*$8,191,787*	*$8,274,368*	*$1,982,033*	$29,348,237
Infrastructure	$0	$0	$975,000	*$1,925,000*	*$0*	$0	$0	$0	$2,900,000
SLRHC Administrative Costs	$75,000	$300,000	$300,000	*$300,000*	*$75,000*	*$0*	*$0*	*$0*	$1,050,000
SLRHC Administrative Costs Coverage Model			$584,155	*$4,328,950*	$3,692,463	*$4,024,400*	*$3,801,084*	*$950,271*	$17,381,324
CRC Program Administrative Costs	$91,684	$700,000	$700,000	*$700,000*	*$175,000*	*$0*	*$0*	*$0*	$2,366,684
Projected expenditures for DY3 DOS*	$0	$0	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	$0
Actual expenditures for DY3 DOS				$2,670,607	*$33,308*	*$0*	*$0*	*$0*	$2,703,915
Projected expenditures for DY4 DOS*				$0	*$0*	*$199,900*	*$0*	*$0*	$199,900
Actual expenditures for DY4 DOS				$0	*$2,540,653*	*$0*	*$0*	*$0*	$2,540,653
Projected expenditures for DY5 DOS*						*$2,540,366*	*$0*	*$0*	$2,540,366
Total With Waiver Expenditures	**$182,454,255**	**$707,833,062**	**$764,632,976**	**$764,632,976**	**$764,632,976**	**$764,632,976**	**$726,401,327**	**$172,520,315**	**$4,845,200,497**
Amount under (over) the annual waiver cap	$7,227,010	$40,766,549	$0	$0	$0	$0	$0	$0	$50,533,925
Annual expenditure by DY Payment Date as reported on CMS 64s (Demo expenses NOT including residual DSH)			$25,987,982	$28,994,039	$26,374,594	$29,653,686	$26,281,222	$6,335,139	
Annual expenditure authority cap by DY DOS (Demo expenses NOT including residual DSH)	$7,416,684	$28,750,000	$28,691,897	$29,063,985	$26,340,999	$26,913,420	$26,281,222	$6,335,139	

*Amount anticipated to be reported in Demonstration Years that should apply to a previous demonstration period.

**FFY 2012 through FY 2014 DSH allotments have not been finalized. Therefore, the regular FFY 2011 allotment was used as a proxy for FFY 2012 through FFY 2014. DSH allotment is shown as (total computable) above. For reference, DSH allotment in Federal share is shown below:

	FFY 2010
FFY 2010 Allotment (Federal share)	$465,868,922
FFY 2010 Increased Allotment (Federal share)	$23,584,614
Total Allotment (Federal share)	$489,453,536

Note: FFY 2010 FMAP for MO = 64.51%; FFY 2011 FMAP for MO = 63.29%; FFY 2013 FMAP = 61.37%. FFY 2014 FMAP = 62.03; FFY 2015 FMAP= 63.45

Budget Neutrality With Amendment: *Budget neutrality projections are through the end of calendar year 2016, in order to reflect the extension request to be submitted by the State at the end of 2014 in the event the Missouri legislature does not approve Medicaid expansion during its 2015 session.*

Budget Neutrality

Gateway to Better Health (Total Computable)

	DY 1 FFY 2010 07/28/2010 - 09/30/2010	DY 2 FFY 2011 10/01/2010 - 09/30/2011	DY 3 FFY 2012 10/01/2011- 9/30/2012	DY 4 FFY 2013 10/01/2012- 09/30/2013	DY 5 FFY 2014 10/01/2013- 9/30/2014	DY 6 FFY 2015 10/01/2014- 09/30/2015	DY 7 FFY 2016 10/01/2015- 09/30/2016	DY 8 FFY 2017 10/01/2016- 12/31/2016	Total - 6.5 year demonstration 07/28/2010 to 12/31/2015
No. of months in DY	**3 months**	**12 months**	**12 months**	**12 months**	**12 months**	**12 months**	**12 months**	**3 months**	
No. of months of direct payments to facilities	**3 months**	**12 months**	**9 months**	**0 months**	**0 months**	**0 months**	**0 months**	**0 months**	
No. of months of Pilot Program (will be implemented on 07/01/2012)	**0 months**	**0 months**	**3 months**	**12 months**	**12 months**	**12 months**	**12 months**	**3 months**	
Without Waiver Projections									
Estimated DSH Allotment**	$189,681,265	$748,599,611	*$764,632,976*	*$764,632,976*	*$764,632,976*	*$764,632,976*	*$726,401,327*	*$172,520,315*	**$4,895,734,422**
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With Waiver Projections									
Residual DSH	$175,037,571	$679,083,062	*$738,644,994*	*$735,638,937*	*$738,258,382*	*$734,928,380*	*$700,323,723*	*$166,185,174*	$4,668,100,223
St. Louis ConnectCare	$4,850,000	$18,150,000	$14,879,909	*$3,148,648*	$118,489	$0	$0	$0	$41,147,045
Grace Hill Neighborhood Health Centers	$1,462,500	$5,850,000	*$5,071,706*	*$5,016,507*	*$6,073,656*	*$6,690,813*	*$6,418,420*	*$1,551,515*	$38,135,117
Myrtle Davis Comprehensive Health Centers	$937,500	$3,750,000	*$3,097,841*	*$2,108,161*	*$1,838,040*	*$2,472,692*	*$2,372,024*	*$573,386*	$17,149,644
Contingency Provider Network	$0	$0	*$379,372*	*$4,254,902*	*$5,469,199*	*$5,725,193*	*$5,496,984*	*$1,328,778*	$22,654,429
Voucher	$0	$0	$0	*$4,541,262*	*$6,358,786*	*$8,051,231*	*$7,989,092*	*$1,931,191*	$28,871,563
Infrastructure	$0	$0	$975,000	*$1,925,000*	*$0*	$0	$0	$0	$2,900,000
SLRHC Administrative Costs	$75,000	$300,000	$300,000	*$300,000*	*$75,000*	*$0*	*$0*	*$0*	$1,050,000
SLRHC Administrative Costs Coverage Model			$584,155	*$4,328,950*	$3,692,463	*$4,024,400*	*$3,801,084*	*$950,271*	$17,381,324
CRC Program Administrative Costs	$91,684	$700,000	$700,000	*$700,000*	*$175,000*	*$0*	*$0*	*$0*	$2,366,684
Projected expenditures for DY3 DOS*	$0	$0	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	$0
Actual expenditures for DY3 DOS				$2,670,607	*$33,308*	*$0*	*$0*	*$0*	$2,703,915
Projected expenditures for DY4 DOS*				$0	*$0*	*$199,900*	*$0*	*$0*	$199,900
Actual expenditures for DY4 DOS				$0	*$2,540,653*	*$0*	*$0*	*$0*	$2,540,653
Projected expenditures for DY5 DOS*						*$2,540,366*	*$0*	*$0*	$2,540,366
Total With Waiver Expenditures	**$182,454,255**	**$707,833,062**	**$764,632,976**	**$764,632,976**	**$764,632,976**	**$764,632,976**	**$726,401,327**	**$172,520,315**	**$4,845,200,497**
Amount under (over) the annual waiver cap	$7,227,010	$40,766,549	$0	$0	$0	$0	$0	$0	$50,533,925
Annual expenditure by DY Payment Date as reported on CMS 64s (Demo expenses NOT including residual DSH)			$25,987,982	$28,994,039	$26,374,594	$29,704,596	$26,077,604	$6,335,141	
Annual expenditure authority cap by DY DOS (Demo expenses NOT including residual DSH)	$7,416,684	$28,750,000	$28,691,897	$29,063,985	$26,340,999	$26,964,330	$26,077,604	$6,335,141	

*Amount anticipated to be reported in Demonstration Years that should apply to a previous demonstration period.

**FFY 2012 through FY 2014 DSH allotments have not been finalized. Therefore, the regular FFY 2011 allotment was used as a proxy for FFY 2012 through FFY 2014. DSH allotment is shown as (total computable) above. For reference, DSH allotment in Federal share is shown below:

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Note: FFY 2010 FMAP for MO = 64.51%; FFY 2011 FMAP for MO = 63.29%; FFY 2013 FMAP = 61.37%. FFY 2014 FMAP = 62.03; FFY 2015 FMAP= 63.45

The budget neutrality assumes the amendment to iinclude certain brand name drugs that do not have a generic equivalent is approved.