

**Public Notice to Amend Missouri’s Gateway to Better Health Section 1115 Demonstration
Project to Add a Substance Use Treatment Benefit Number: 11-W-00250/7**

July 31, 2018

Pursuant to provisions of Title 42 Code of Federal Regulations (CFR) 431.408, which mandate that an application, an extension of an existing demonstration project, or waiver amendment that the State intends to submit to Centers for Medicare and Medicaid Services (CMS) for review and consideration be published and made available for review and comment, this is to advise that:

1. The State of Missouri, Department of Social Services (DSS), provides notice of the following:

To ensure efficiency, economy, quality of care, and access, the MO HealthNet Division (MHD) provides notice of the intent to amend the Gateway to Better Health Demonstration to add a Substance Use Disorder (SUD) treatment benefit. A copy of the full amendment request under consideration may be found at <http://dss.mo.gov/mhd/>. The Gateway to Better Health Demonstration is designed to provide coverage to uninsured adults residing in St. Louis City and St. Louis County, who are between the ages of 19 and 64, with family incomes between 0 and 100 percent of the Federal poverty level (FPL), and who do not qualify for Medicaid. The Demonstration is set to expire on December 31, 2022; however, should the State opt to expand Medicaid during the extension period to cover this population, the Demonstration will terminate immediately.

The State is requesting authority to extend the benefits for the population covered by the Demonstration to include office visits and certain generic prescriptions for SUD treatment. Diagnoses for which these new services may be available include:

- alcohol related disorders,
- opioid related disorders,
- cannabis related disorders,
- cocaine related disorders,
- inhalant related disorders, and
- hallucinogen related disorders.

The State also proposes to decrease the cap on enrollment in the Demonstration from 21,432 to 15,500. Finally, the State seeks to amend the Demonstration to clarify that it is not expected to claim rebates from manufacturers for drugs purchased through the Demonstration.

I. Program Description and Goals

On July 28, 2010, CMS approved the State of Missouri’s “Gateway to Better Health” Demonstration, which includes the following main objectives:

- 1) 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;
- 2) Transition the “St. Louis model” to a coverage model as opposed to a direct payment model by July 1, 2012;

- 3) 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;
- 4) Maintain and enhance quality service delivery strategies to reduce health disparities; and
- 5) For the first two years of the Demonstration, ensure that there is a 2 percent increase in the number of uninsured persons receiving services at St. Louis ConnectCare, Affinia Healthcare (formerly known as Grace Hill Health Centers) and CareSTL Health (formerly known as Myrtle Hilliard Davis Comprehensive Health Centers).

For the first two years of the Demonstration, certain providers were paid directly for uncompensated care. These providers included St. Louis ConnectCare, Affinia Healthcare (formerly known as Grace Hill Health Centers) and CareSTL Health (formerly known as Myrtle Hilliard Davis Comprehensive Health Centers). As of July 1, 2012, the program transitioned to a coverage model.

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 through a coverage model.

The Pilot Program is designed to provide primary, urgent and specialty care coverage to uninsured¹ adults in St. Louis City and St. Louis County, aged 19-64, who are below 100 percent of the FPL through a coverage model known as Gateway to Better Health. The Demonstration also includes a performance and incentive structure for the primary care providers and tracks health outcomes.

Under the Demonstration, the State has authority to claim as administrative costs limited amounts incurred for the functions related to the design and implementation of the Demonstration pursuant to a Memorandum of Understanding with the St. Louis Regional Health Commission (SLRHC), which is a non-profit, non-governmental organization whose mission is to:

- 1) Increase access to health care for people who are medically uninsured and underinsured;
- 2) Reduce health disparities among populations in St. Louis City and County; and
- 3) Improve health outcomes among populations in St. Louis City and County, especially among those most at risk.

This Demonstration Project and the funding mechanisms that preceded it have been critical to maintaining and improving access to health care for uninsured individuals in St. Louis City and County since the closure of the city's last remaining public hospital in 1997.

CMS offers additional information about Section 1115 waivers generally and the Gateway waiver specifically at:

<http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/Waivers.html>.

The objectives for the Demonstration continue to be:

- 1) Preserve and strengthen the St. Louis City and St. Louis County safety net of health care providers available to serve the uninsured.

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.

- 2) Connect the uninsured to a primary care home, which will enhance coordination, quality and efficiency of health care through patient and provider involvement.
- 3) Maintain and enhance quality service delivery strategies to reduce health disparities.

II. Beneficiaries and Eligibility Criteria

Gateway to Better Health will continue to provide access to primary care, specialty care, urgent care, and will continue to be available to individuals who meet the following requirements:

- A citizen of the United States; legal immigrant who has met the requirements for the five-year waiting period for Medicaid benefits; refugee or asylee under same immigrant eligibility requirements that apply to the Medicaid program
- A resident of St. Louis City or St. Louis County
- Ages 19 through 64
- Uninsured
- At or below the FPL of 100%
- Not eligible for coverage under the federal Medicare program or Missouri Medicaid
- Patients with a primary care home at one of the in network primary care sites.

III. Delivery System

Gateway to Better Health services are provided through a limited provider network. Beneficiaries will continue to choose a primary care home in which to enroll. Primary care homes in the network include:

- BJK People's Health Centers
- Family Care Health Centers
- Affinia Healthcare (formerly known as Grace Hill Health Centers)
- CareSTL Health (formerly known as Myrtle Hilliard Davis Comprehensive Health Centers)
- St. Louis County Department of Public Health

Primary care provider organizations will continue to be paid under an alternative payment methodology.

For specialty care, beneficiaries may be referred by their primary care physician for specialty care services at a participating specialty care provider, including for physician inpatient services or outpatient hospital care. Specialty care providers will continue to be paid for on a fee-for-service basis for care provided to all Gateway beneficiaries.

With the newly proposed SUD treatment benefit, patients would be able to receive treatment (medications and other services) for substance use at their health center without any further administrative requirements or changes in payment methodology.

IV. Existing Benefits

Beneficiaries enrolled in Gateway to Better Health will continue to receive the following benefits:

Preventative; wellcare; dental (diagnostic, preventive); internal and family practice medicine (up to 5 five urgent care visits); gynecology; podiatry; generic prescriptions dispensed at primary

care clinics as well as brand name insulin and inhalers; cardiology; durable medical equipment (DME) (on a limited basis); endocrinology; ear nose and throat (ENT); gastroenterology; neurology; oncology, radiation therapy, rheumatology, and laboratory/pathology services; ophthalmology; orthopedics; outpatient surgery; physical, occupational or speech therapy (on a limited basis); pulmonology; radiology (x-ray, Magnetic Resonance Imaging [MRI], Positron Emission Tomography [PET]/Computed Tomography [CT] scans); renal; urology; and non-emergency medical transportation (NEMT).

V. Proposed New Benefits Under the Amendment

In addition to this list of existing benefits, the amendment would give the State the authority to add a substance use treatment benefit, which would cover office visits and generic prescriptions for substance use treatment, specifically for the disorders listed in Table 1. Currently, the Demonstration covers tobacco cessation counseling provided at the primary care centers, but no other substance use treatments (drugs or interventions) are covered. All pharmaceuticals covered by the Demonstration, including the additional drugs for substance use treatment, would continue to be dispensed by the patients' primary care homes and covered in the alternative payment used to reimburse community health centers for medical and dental services and pharmaceuticals.

Annually, on average between 2005 and 2010, 9.5 percent or 219,000 people aged 12 or older in the St. Louis Metropolitan Statistical Area (MSA) were classified as having a SUD. In the entire state of Missouri, this metric was estimated to be 8.9 percent of the population or approximately 433,000 individuals (Substance Abuse and Mental Health Services Administration, 2012). According to the Missouri Department of Mental Health, in 2008, the average cost to treat a substance addicted individual was \$1,346, compared to a \$17,300 cost to society not to treat the individual. The SUD treatment benefit would be of great value to the St. Louis City and St. Louis County by expanding access to treatment services and reducing overall costs to society.

Prior to this amendment, some patients enrolled in Gateway had access to SUD treatment through avenues outside of the demonstration, such as through health centers' sliding fee scales; pharmaceutical manufacturers' Prescription Assistance Programs (PAPs); and behavioral health safety net providers. By covering the generic drugs listed below in Table 2 and services listed in Table 3, patients would be able to receive treatment at their health center without any further administrative requirement and at a lower cost than the sliding fee scale.

Furthermore, SUD treatment is directly related to the Demonstration's evaluation and incentive measures, which are designed to improve the health of the uninsured and underinsured population in the St. Louis region.

This amendment request is being made after significant consultation with the program's providers, patients, and other community stakeholders, who indicated that SUD treatment is a top priority for the Gateway patient population. After consulting these stakeholders, it was determined that adding a SUD treatment benefit to the Demonstration's benefit package would reduce barriers for patients in accessing these interventions, which are critical to reducing health disparities and to reducing preventable emergency department visits and hospitalizations.

Table 1: Diagnosis Codes (First Three Digits)

ICD10 Code	Description
F10	Alcohol related disorders
F11	Opioid related disorders
F12	Cannabis related disorders
F13	Sedative, hypnotic, or anxiolytic related disorders
F14	Cocaine related disorders
F15	Other stimulant related disorders
F16	Hallucinogen related disorders
F17	Nicotine dependence
F18	Inhalant related disorders

Table 2: Generic Drugs Included

Drug
Baclofen
Buprenorphine HCl
Buproban
Bupropion HCL, Bupropion HCL SR , Bupropion XI
Desipramine HCL
Disulfiram
Gabapentin
Mirtazapine
Naltrexone HCL
Paroxetine CR, Paroxetine ER, Paroxetine HCL
Topiramate

Table 3: CPT and HCPC Procedure Codes

Code	Description
3016F	Patient screened for unhealthy alcohol use using a systematic screening method
90791	Psychiatric diagnostic evaluation
90792	Psychiatric diagnostic evaluation with medical services
90832	Psychotherapy, 30 minutes with patient
90833	Psychotherapy, 30 minutes with patient when performed with an evaluation and management service (List separately in addition to the code for primary procedure)
90834	Psychotherapy, 45 minutes with patient
90837	Psychotherapy, 60 minutes with patient
90839	Psychotherapy for crisis; first 60 minutes
90846	Family psychotherapy (without the patient present), 50 minutes
90847	Family psychotherapy (conjoint psychotherapy) (with patient present), 50 minutes
90849	Multiple-family group psychotherapy
90853	Group psychotherapy (other than of a multiple-family group)

90875	Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (eg, insight oriented, behavior modifying or supportive psychotherapy); 30 minutes
90887	Interpretation or explanation of results of psychiatric, other medical examinations and procedures, or other accumulated data to family or other responsible persons, or advising them how to assist patient
90899	Unlisted psychiatric service or procedure
96101	Psychological testing (includes psychodiagnostic assessment of emotionality, intellectual abilities, personality and psychopathology, e.g., MMPI, Rorschach, WAIS), per hour of the psychologist's or physician's time, both face-to-face time administering tests to the patient and time interpreting these test results and preparing the report
96102	Psychological testing (includes psychodiagnostic assessment of emotionality, intellectual abilities, personality and psychopathology, e.g., MMPI and WAIS), with qualified health care professional interpretation and report, administered by technician, per hour of technician time, face-to-face
96103	Psychological testing (includes psychodiagnostic assessment of emotionality, intellectual abilities, personality and psychopathology, e.g., MMPI), administered by a computer, with qualified health care professional interpretation and report
96150	Health and behavior assessment (e.g., health-focused clinical interview, behavioral observations, psychophysiological monitoring, health-oriented questionnaires), each 15 minutes face-to-face with the patient; initial assessment
96151	Health and behavior assessment (e.g., health-focused clinical interview, behavioral observations, psychophysiological monitoring, health-oriented questionnaires), each 15 minutes face-to-face with the patient; reassessment
96153	Health and behavior intervention, each 15 minutes, face-to-face; group (2 or more patients)
G0396	Alcohol and/or substance (other than tobacco) abuse structured assessment (e.g., AUDIT, DAST), and brief intervention 15 to 30 minutes
G0442	Annual alcohol misuse screening, 15 minutes
G0443	Brief face-to-face behavioral counseling for alcohol misuse, 15 minutes
G0444	Annual depression screening, 15 minutes
H0001	Alcohol and/or drug assessment
H0002	Behavioral health screening to determine eligibility for admission to treatment program
H0004	Behavioral health counseling and therapy, per 15 minutes
H0005	Alcohol and/or drug services; group counseling by a clinician
H0006	Alcohol and/or drug services; case management
H0024	Behavioral health prevention information dissemination service (one-way direct or non-direct contact with service audiences to affect knowledge and attitude)
H0025	Behavioral health prevention education service (delivery of services with target population to affect knowledge, attitude and/or behavior)
H0031	Mental health assessment, by non-physician
H0032	Mental health service plan development by non-physician
H0035	Mental health partial hospitalization, treatment, less than 24 hours
H0038	Self-help/peer services, per 15 minutes
H0039	Assertive community treatment, face-to-face, per 15 minutes
H0040	Assertive community treatment program, per diem
H0046	Mental health services, not otherwise specified
H0048	Alcohol and/or other drug testing: collection and handling only, specimens other than blood

H0050	Alcohol and/or drug services, brief intervention, per 15 minutes
H2011	Crisis intervention service, per 15 minutes
H2012	Behavioral health day treatment, per hour
H2019	Therapeutic behavioral services, per 15 minutes
H2021	Community-based wrap-around services, per 15 minutes
H2036	Alcohol and/or other drug treatment program, per diem
S9480	Intensive outpatient psychiatric services, per diem
S9484	Crisis intervention mental health services, per hour
S9485	Crisis intervention mental health services, per diem
T1007	Alcohol and/or substance abuse services, treatment plan development and/or modification

VI. Medicaid Drug Rebates

In addition to adding a SUD benefit, the State seeks to amend the Demonstration to expressly clarify that it is not required to seek rebates from manufacturers for drugs covered through Gateway. It would be challenging for the State to claim rebates on the physician-administered drugs covered by the Demonstration, as Gateway reimburses both participating community health centers and specialty providers at the Medicare rate. Medicare does not pay a drug rebate and the Gateway claims processing system is not set up to require the National Drug Code numbers that would allow the Department to claim rebates. Moreover, reprogramming the system to be able to claim rebates would not be cost-effective, given: the small size of the Gateway program,; the limited benefit package available to Gateway enrollees; the fact that most covered drugs are generics (and thus qualify for a lower rebate amount than innovator drugs); and the fact that four of the five health community clinics that participate in Gateway also participate in the 340B program, and thus any drugs dispensed through them are not eligible for rebates.

VII. Cost Sharing

There is no premium for Gateway to Better Health. Beneficiary co-pays are the same as those for patients of Missouri Medicaid, MO HealthNet. The amendment would not change this.

VIII. Aggregate and Historical Budgetary and Expenditure Data

Under the current Demonstration, the State is authorized to spend up to \$30 million (total computable) annually in lieu of spending that amount of statutorily authorized funding on payments to disproportionate share hospitals (DSHs). The amendment would not change this authorization.

IX. Financial Analysis and Anticipated Changes in Enrollment

With an anticipated implementation date of January 1, 2019, the five community health centers in the Gateway to Better Health network would receive an estimated additional \$13.11 per member per month (PMPM) to cover office visits and generic prescriptions for substance use treatment in 2019. The non-federal share of these additional Demonstration expenditures will come from appropriations from St. Louis County, which recently announced additional funding for SUD services.

The Wakely Consulting Group was engaged to determine the PMPM rate, and to estimate the financial impact of the amendment over the course of the demonstration. Wakely Consulting’s estimates are shown in Table 4:

Table 4: Cost Projection and Covered Members Estimated 2019-2022 (Any Diagnosis)

Services	2019	2020	2021	2022
Clinic capitation PMPM	\$67.86	\$70.58	\$73.40	\$76.34
Transportation PMPM	\$1.30	\$1.30	\$1.30	\$1.30
FFS PMPM	\$42.76	\$43.83	\$44.92	\$46.05
Substance Use PMPM	\$13.11	\$13.72	\$14.37	\$15.06
Total PMPM	\$125.03	\$129.43	\$133.99	\$138.75
Proposed Enrollment Cap	15,500	15,500	15,500	15,500
Projected Expenditures	\$23,255,580	\$24,073,980	\$24,922,140	\$25,807,500

The program would 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. The Demonstration has an enrollment cap of 21,432, but program membership has averaged 14,892 over the past year, and current enrollment is approximately 14,300. To bring the cap closer to the Demonstration’s historic enrollment and to ensure there is sufficient funding to cover all Demonstration benefits, including the new SUD services, the State proposes to lower the enrollment cap to 15,500, effective January 1, 2019.

X. Waiver and Expenditure Authorities

It is anticipated the Waiver and Expenditure Authorities would include:

- **Demonstration Population 1:** Effective January 1, 2014, expenditures for uninsured individuals, not eligible for Medicaid, who are living in St. Louis City or St. Louis County, and are between the ages of 19-64 years of age with income up to 100 percent of the FPL to pay for primary care provided by a designated primary care provider or specialty care provider when referred by a designated primary care provider.
- **Expenditure for Managing the Coverage Model:** Effective January 1, 2014, expenditures pursuant to a memorandum of understanding and not to exceed \$4,500,000 for costs incurred by the SLRHC to activities related to the continued administration of the coverage model.

The state also seeks continued waivers of the following Medicaid requirements:

Statewideness

Section 1902(a)(1)

To the extent necessary, to allow the State to limit enrollment in the Demonstration to persons residing in St. Louis City and St. Louis County.

Reasonable Promptness

Section 1902(a)(8)

To the extent necessary, to enable the State to establish an enrollment target and maintain waiting lists for the Demonstration population.

Amount, Duration and Scope**Section 1902(a)(10)(B)**

To the extent necessary, to permit the State to offer benefits that differ among the Demonstration population and that differ from the benefits offered under the Medicaid state plan.

Freedom of Choice**Section 1902(a)(23)(A)**

To the extent necessary, to enable the State to mandatorily enroll the Demonstration population into a delivery system that restricts free choice of provider.

Retroactive Eligibility**Section 1902(a)(34)**

To the extent necessary, to enable the State to not provide medical assistance to the Demonstration population prior to the date of application for the Demonstration benefits.

Payment for Services by Federally Qualified Health Centers (FQHCs)**Section 1902(a)(15)**

To the extent necessary, to enable the State to make payments to participating FQHCs for services provided to Demonstration Population using reimbursement methodologies other than those required by section 1902(bb) of the Act to the limited nature of the benefits.

XI. Evaluation of the Gateway to Better Health Demonstration

The State intends to measure progress against the Demonstration objectives throughout the Demonstration. Interim evaluation activities to date indicate that all Demonstration objectives have been met or significant progress can be demonstrated. Additional activities will evaluate whether or not the coverage model proves out the following hypotheses.

- I. The SLRHC Gateway project supports the availability of primary and specialty health care services to uninsured adults in St. Louis City and St. Louis County.
- II. Connecting and engaging uninsured individuals to a Gateway primary care home corresponds with sustained or increased primary care utilization.
- III. Enhanced provider quality of care corresponds with improved overall health outcomes and reduced health disparities.

The current Evaluation Design requires tracking a number of quality measures that could be impacted by the implementation of this amendment. These measures include but are not limited to the following metrics:

- Available primary care services – number and type of primary care services endorsed by Gateway providers in primary care services
- Barrier to healthcare self-report – percentage of enrollees who report barriers to healthcare without Gateway program
- Barrier to healthcare provider report – percentage of providers who report enrollee barriers to healthcare without Gateway program
- Medical service line utilization – average number of office visits per Gateway enrollee

- Wellness self-report – percentage of providers who report improved Gateway enrollee health
- Tobacco use and assessment and cessation intervention – percentage of Gateway enrollees assessed for tobacco use and, if identified as a tobacco user, received cessation counseling and/or pharmacotherapy

Additionally, to measure the impact of this benefit, the following annual measures will be added to the Evaluation Design:

- Number of encounters with SUD as the primary or secondary diagnosis
 - Number of users with SUD as the primary or secondary diagnosis
 - Number of covered drugs (see Table 2) prescribed to treat SUD
 - Percent of patients prescribed a medication for alcohol use disorder (AUD)
 - Percent of patients prescribed a medication for opioid use disorder (OUD)
2. Comments may be sent by regular mail, express or overnight mail, in person or by courier within thirty days after publication of this notice and must be sent or delivered to the following address:

MO HealthNet Division
 615 Howerton Ct., 2nd Floor
 Jefferson City, MO 65109
 Attention: Sara Davenport

Comments may also be emailed to Ask.MHD@dss.mo.gov. Please use **“Public Comment for Gateway to Better Health Section 1115 Demonstration Project”** in the subject line. Comments must be received by **August 30, 2018**.

3. A copy of the full amendment request under consideration for Gateway to Better Health Section 1115 Demonstration Project to Add a SUD Treatment Benefit Number: 11-W-00250/7 is available for public view by contacting the DSS, MHD at Ask.MHD@dss.mo.gov. These documents may also be viewed online at <https://dss.mo.gov/mhd/waivers/1115-demonstration-waivers/gateway-to-better-health.htm>.

Appointments may be made to view a hard copy of the full public notice document as well as a draft of the amendment application. Appointments may be made during regular business hours 8:00 A.M. to 4:30 P.M., Monday through Friday, by calling (314) 446-6454, ext. 1032. Appointments to view the documents will take place at 1113 Mississippi Avenue, St. Louis, MO 63104.

CMS offers general information about Section 1115 waivers and the Gateway Waiver specifically at <http://www.medicaid.gov/Medicaid-CHIP-Program-information/BY-Topics/Waivers/Waivers.html>.

Public hearings are scheduled for:

Tuesday, August 7, 2018, 7:30 – 8:30 AM*
 Ethical Society of St. Louis
 9001 Clayton Road, St. Louis, MO 63117

Wednesday, August 8, 2018, 3:30 - 4:30 PM*
 Forest Park Visitor and Education Center
 Voyagers Room
 5595 Grand Drive St. Louis, MO 63112

** Individuals wanting to participate in the public hearing via conference call may dial 888-808-6929, access code: 9158702.*

The State and the St. Louis Regional Health Commission will accept verbal and written comments at the public hearings. The outcome of this process and the input provided will be summarized for CMS upon submission of the notification of request for a Demonstration amendment.