Application for

Section 1915(b) (4) Waiver
Fee-for-Service
Selective Contracting Program

June, 2012

v1.0

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Fee-for-Service (FFS) Selective Contracting Program

Facesheet

The **State** of Nevada requests a waiver/amendment under the authority of Section 1915(b) of the Act. The Medicaid agency will directly operate the waiver.

The **name of the waiver program** is Specialty Pharmacy Drug Program.
(List each program name if the waiver authorizes more than one program.).

Type of request. This is:
_x_ an initial request for new waiver. All sections are filled.
___ a request to amend an existing waiver, which modifies Section/Part ____.
___ a renewal request
Section A is:
___ replaced in full
___ carried over with no changes
___ changes noted in **BOLD**.

Section B is:
___ replaced in full.
___ changes noted in **BOLD**.

Effective Dates: This waiver is requested for a period of five years beginning ~~January~~ July 1, 2021 and ending ~~December~~ June 30~~1~~, 2026~~5~~.

State Contact: The State contact person for this waiver is David Olsen~~Holly Long~~, Division of Health Care Financing and Policy~~ ((~~DHCFP~~) Pharmacy~~, Chief of Supervising Social Services Program Specialist~~Pharmacy Services,~~)~~ ~~and~~ who can be reached by telephone at (775) 684-3623 (office)~~3150,, or fax at~~ (775) 400~~684~~-6451 (cell)~~3893~~, or e-mail at david.olsen~~hlong~~@dhcfp.nv.gov. DuAne Young, ~~(~~DHCFP Deputy Administrator, may also be contacted at~~)~~ (775) 684-3679 (office), (775) 721-4408 (cell), or email at dyoung@dhcfp.nv.gov.

Section A – Waiver Program Description

Part I: Program Overview

Tribal Consultation:
Describe the efforts the State has made to ensure that Federally-recognized tribes in the State are aware of and have had the opportunity to comment on this waiver proposal.

The Division of Health Care Financing and Policy (hereafter referred to as the "DHCFP") sent tribal notifications on August 28, 2020 to the federally recognized tribes in Nevada regarding the 1915(b)(4) waiver proposing the Nevada Medicaid Specialty Pharmacy Drug Program. In addition to this notification, the DHCFP ~~is scheduled to~~ presented information regarding the Nevada Medicaid Specialty Drug Program at the ~~upcoming~~ Tribal Consultation meeting on October 7, 2020. Tribal members are exempt from mandatory enrollment into Nevada Medicaid Specialty Pharmacy Drug Program. A copy of the ~~August 28, 2020~~April 8, 2021 letter to the Tribal representatives is provided as an attachment.

Program Description:
Provide a brief description of the proposed selective contracting program or, if this is a request to amend an existing selective contracting waiver, the history of and changes requested to the existing program. Please include the estimated number of enrollees served throughout the waiver.

The DHCFP has chosen to implement a Specialty Pharmacy Drug Program. The program will lock-in and require Fee-for-Service (FFS) beneficiaries and providers to acquire selected specialty medications by mail order through contracted specialty pharmacies. These pharmacies ship the medications directly to the site of administration (e.g., physician's office, beneficiaries' home). The State pays the specialty pharmacies based on pricing negotiated per contract.

The contracted Specialty Pharmacy Drug Program will provide beneficiaries and providers with clinical support to ensure optimal therapy management. This clinical support includes, but is not limited to, regular monthly calls to beneficiaries by a care coordinator to track adherence and health status and maintenance of a 24-hour call center with clinical staff to address beneficiary and provider concerns. The program will provide care management involving close monitoring of side effects and response to treatment which is essential for optimizing beneficiary use of specialty medications and managing costs.

The program will be operated by the current FFS contracted Pharmacy Benefit Manager (PBM), OptumRx, utilizing their OptumRx specialty pharmacies, call centers, care coordinators and distribution centers.

This application requests a five-year waiver approval for selective contracting for implementation of a Specialty Pharmacy Drug Program.

The estimated number of enrollees (at a given time) projected to be served by the Specialty Pharmacy Drug Program throughout this waiver is approximately ~~377~~ 360 individuals.

Waiver Services:
Please list all existing State Plan services the State will provide through this selective contracting waiver.

The Nevada Medicaid Specialty Drug Program will provide prescription medication management for beneficiaries diagnosed and being treated for hemophilia, hepatitis C or intravenous immunoglobulin (IVIG).

A. Statutory Authority

1. **Waiver Authority.** The State is seeking authority under the following subsection of 1915(b):

   _x_ **1915(b) (4) - FFS Selective Contracting program**

2. **Sections Waived.** The State requests a waiver of these sections of 1902 of the Social Security Act:

   a.___ **Section 1902(a) (1) - State Wideness**
   b.___ **Section 1902(a) (10) (B) - Comparability of Services**
   c._x_ **Section 1902(a) (23) - Freedom of Choice**
   d.___ **Other Sections of 1902** – (please specify)

B. Delivery Systems

1. **Reimbursement.** Payment for the selective contracting program is:

   ___ the same as stipulated in the State Plan
   _x_ is different than stipulated in the State Plan (please describe)

Pricing for specialty drugs or drug classes will be negotiated between the state and the supplier. The initial drug classes included in the Specialty Pharmacy Drug Program include Hemophilia, Hepatitis C, and IVIG. The negotiated drug price for these initial classes guarantees the Wholesale Acquisition Cost (WAC) – 9.5%. All specialty drugs not included in the pricing guarantee will be priced utilizing the lessor of pricing logic currently included in the state plan.

2. **Procurement**. The State will select the contractor in the following manner:

   _x_ **Competitive** procurement
   ___ **Open** cooperative procurement
   ___ **Sole source** procurement
   ___ **Other** (please describe)

C. Restriction of Freedom of Choice

1. **Provider Limitations**.

_x_ Beneficiaries will be limited to a single provider in their service area.
___ Beneficiaries will be given a choice of providers in their service area.

(NOTE: Please indicate the area(s) of the State where the waiver program will be implemented)

The waiver program will be implemented statewide.

2. **State Standards.**

Detail any difference between the state standards that will be applied under this waiver and those detailed in the State Plan coverage or reimbursement documents.

The difference in state standards that will be applied under this waiver include mail order delivery for medications, a unique pricing algorithm which will only apply to the specialty drugs indicated in this waiver and in the State Plan Amendment to follow. Additionally, a dispensing fee will not be covered.

D. Populations Affected by Waiver

(May be modified as needed to fit the State's specific circumstances)

1. **Included Populations**. The following populations are included in the waiver:

_x_ Section 1931 Children and Related Populations
_x_ Section 1931 Adults and Related Populations
_x_ Blind/Disabled Adults and Related Populations
_x_ Blind/Disabled Children and Related Populations
_x_ Aged and Related Populations
_x_ Foster Care Children
_x_ Title XXI CHIP Children

2. **Excluded Populations.** Indicate if any of the following populations are excluded from participating in the waiver:

___ Dual Eligibles
___ Poverty Level Pregnant Women
___ Individuals with other insurance
_x_ Individuals residing in a nursing facility or ICF/MR
_x_ Individuals enrolled in a managed care program
___ Individuals participating in a HCBS Waiver program
_x_ American Indians/Alaskan Natives
___ Special Needs Children (State Defined). Please provide this definition.
___ Individuals receiving retroactive eligibility
___ Other (Please define):

Part II: Access, Provider Capacity and Utilization Standards

A. Timely Access Standards

Describe the standard that the State will adopt (or if this is a renewal or amendment of an existing selective contracting waiver, provide evidence that the State has adopted) defining timely Medicaid beneficiary access to the contracted services, *i.e.*, what constitutes timely access to the service?

The selected Specialty Pharmacy Drug Program contracted vendor will provide beneficiaries, physicians and any other appropriate health care providers access to clinical hemophilia, hepatitis C and IVIG specialists 24 hours a day, seven days a week through a toll-free telephone number. Calls must be responded to promptly and accurately.

Nevada beneficiaries included in the program will be supported by a skilled care team led by a clinical pharmacist or clinical nurse as well as care coordinators. The Specialty Pharmacy care team will be disease state-specific and specially trained to manage any challenge that could impact the clinical, psychosocial or financial status of the beneficiary.

Providers have access to a provider portal which provides access to a beneficiary's contact and treatment team information. Providers may access referral information, prescription status, dispensing locations, prior authorization status, insurance information, current medications, allergy information, diagnoses and provider assessments.

The contracted vendor is required by contract to adhere to specific performance standards. These performance standards include (but are not limited to) call center performance (wait times, number of calls), telephone encounter data (number of calls with medical staff needed for resolution), delivery performance, and dosing compliance. These performance standards will be monitored by the DHCFP through monthly reports.

Availability of emergency delivery services will be provided.

1. How does the State measure (or propose to measure) the timeliness of Medicaid beneficiary access to the services covered under the selective contracting program?

The State will measure the timeliness of Medicaid beneficiary access to the service covered under the selective contracting program by requiring that the contracted vendor provide monthly reports that include the following information: call center performance (wait times, number of calls), telephone encounter data (number of calls with medical staff needed for resolution), delivery statistics, dosing compliance, and claims summary data. The DHCFP will continue to evaluate this report list and modify it as needed in order to meet the needs of the program.

The contracted vendor will ensure sufficient product quantity and inventory to maintain adequate supply for ongoing beneficiary needs.

2. Describe the remedies the State has or will put in place in the event that Medicaid beneficiaries are unable to access the contracted service in a timely fashion.

If a Medicaid beneficiary is unable to access the contracted service in a timely fashion the contracted vendor has an established call center with phone availability 24 hours a day, seven days a week. The contracted vendor has the resources to arrange for emergency supplies when needed and appropriate. The DHCFP may direct the call center to override a system edit as needed to allow a Medicaid beneficiary access to services through a pharmacy included in the contracted program.

If the contracted vendor does not provide the services mandated by contract, an incident report will be created and submitted by the DHCFP to DXC (DHCFP Fiscal Agent & PBM Manager) and OptumRx (PBM). If the contracted vendor continues to demonstrate a pattern of non-compliance with the provisions of services within contract, a corrective action plan will be issued.

B. Provider Capacity Standards

Describe how the State will ensure (or if this is a renewal or amendment of an existing selective contracting waiver, provide evidence that the State has ensured) that its selective contracting program provides a sufficient supply of contracted providers to meet Medicaid beneficiaries' needs.

1. Provide a detailed capacity analysis of the number of providers (e.g., by type, or number of beds for facility-based programs), or vehicles (by type, per contractor for non-emergency transportation programs), needed per location or region to assure sufficient capacity under the selective contracting program.

The Specialty Pharmacy Drug Program currently has 11 enrolled pharmacies. This is subject to change; however, the contracted vendor will notify the DHCFP when any changes to the list occur. All 11 pharmacies are designated distribution centers and two of the 11 are also contact centers.

Specialty medications will be provided by mail order through contracted specialty pharmacies. These pharmacies ship the medications directly to the site of administration (e.g., physician's office, beneficiary's home). If an authorization is denied or the provider requires additional information, they may contact the vendor's Call Center. The contracted vendor's Call Center can override an authorization for emergency situations.

Nevada beneficiaries included in the program will be supported by a skilled care team led by a clinical pharmacist or clinical nurse as well as care coordinators. The Specialty Pharmacy care team will be disease state-specific and specially trained to manage any challenge that could impact the clinical, psychosocial or financial status of the beneficiary.

2. Describe how the State will evaluate and ensure on an ongoing basis that providers are appropriately distributed throughout the geographic regions covered by the

selective contracting program so that Medicaid beneficiaries have sufficient and timely access throughout the regions affected by the program.

The DHCFP and the contracted vendor have reporting systems designed to monitor access in the FFS delivery system and provide oversight of the access in the delivery system.

C. Utilization Standards

Describe the State's utilization standards specific to the selective contracting program.

1. How will the State (or if this is a renewal or amendment of an existing selective contracting waiver, provide evidence that the State) regularly monitor(s) the selective contracting program to determine appropriate Medicaid beneficiary utilization, as defined by the utilization standard described above?

The contracted vendor is required by contract to adhere to specific performance standards. These performance standards include (but are not limited to) call center performance (wait times, number of calls), telephone encounter data (number of calls with medical staff needed for resolution), delivery performance, and dosing compliance. These performance standards will be monitored by the DHCFP through monthly reports.

The contracted vendor will be responsible for providing monthly reports to the DHCFP that include the following information: call center performance (wait times, number of calls), telephone encounter data (number of calls with medical staff needed for resolution), delivery statistics, dosing compliance, and claims summary data. The DHCFP will regularly evaluate this detailed reporting and modify it as needed in order to meet the needs of the program.

2. Describe the remedies the State has or will put in place in the event that Medicaid beneficiary utilization falls below the utilization standards described above.

The contracted vendor has identified that there are an estimated 3607~~7~~ (based on 2019 enrollment data) FFS beneficiaries that may be impacted by this waiver and included in the utilization.

If the utilization falls below the standards, an incident report will be created and submitted by the DHCFP to DXC (DHCFP Fiscal Agent & PBM Manager) and OptumRx (PBM). If the contracted vendor continues to demonstrate a pattern of non-compliance with the provisions of services within contract, a corrective action plan will be issued. Action plans for performance improvement will be required for the standard that has been previously noted as a programmatic trend and/or area that continues to lack significant improvement.

Part III: Quality

A. Quality Standards and Contract Monitoring

1. Describe the State's quality measurement standards specific to the selective contracting program.

    a. Describe how the State will (or if this is a renewal or amendment of an existing selective contracting waiver, provide evidence that the State):

        i. Regularly monitor(s) the contracted providers to determine compliance with the State's quality standards for the selective contracting program.

The State's quality standards include: the Specialty Pharmacy Drug Program will support continuity of care during the implementation of the program which carries over into the ongoing program services, beneficiaries will receive prescribed medications for the selected treatments via mail order/delivery directly to the site of administration on time and they will receive effective treatment management. Additionally, beneficiaries will have access to treatment support and care coordinators through an established call center with phone availability 24 hours a day, seven days a week.

The State's quality standard requires improved cost management by demonstration of cost savings through the Specialty Pharmacy Drug Program.

Monthly reports will be provided to the DHCFP by the Specialty Pharmacy contracted vendor that will include call center performance (wait times, number of calls), telephone encounter data (number of calls with medical staff needed for resolution), delivery statistics, dosing compliance, and claims summary data. These reports will allow the DHCFP to monitor and ensure contract requirements are being fulfilled.

Additionally, supplemental reports or summaries may be requested and provided.

        ii. Take(s) corrective action if there is a failure to comply.

If there is indication of non-compliance or deficiency identified, the DHCFP will request additional information, review and evaluate thoroughly. If the contracted vendor does not provide the services mandated by contract, an incident report will be created and submitted by the DHCFP to DXC (DHCFP Fiscal Agent & PBM Manager) and OptumRx (PBM). Areas found to be deficient become a focus of future review and analysis of compliance. If the contracted vendor continues to demonstrate a pattern of non-compliance with the provisions of services within contract, a corrective action plan will be issued.

2. Describe the State's contract monitoring process specific to the selective contracting program.

    a. Describe how the State will (or if this is a renewal or amendment of an existing selective contracting waiver, provide evidence that the State):

i. Regularly monitor(s) the contracted providers to determine compliance with the contractual requirements of the selective contracting program.

The DHCFP will consistently monitor the program and performance standards by reviewing the monthly reports, request supplemental reports as needed, collect and communicate provider/beneficiary feedback, hold regular meetings with the contracted vendor and the PBM Management, and taking further action as needed to ensure contract compliance.

The DHCFP may issue guidance and/or administrative directives to the contracted vendor and the PBM Management to address identified concerns and provide additional opportunities for evaluating compliance.

ii. Take(s) corrective action if there is a failure to comply.

If the contracted vendor does not provide the services mandated by contract, an incident report will be created and submitted by the DHCFP to DXC (DHCFP Fiscal Agent & PBM Manager) and OptumRx (PBM). Areas found to be deficient become a focus of future review and analysis of compliance. If the contracted vendor continues to demonstrate a pattern of non-compliance with the provisions of services within contract, a corrective action plan will be issued.

B. Coordination and Continuity of Care Standards

Describe how the State assures that coordination and continuity of care is not negatively impacted by the selective contracting program.

The DHCFP intends to implement this Specialty Pharmacy Drug Program with the necessary beneficiary and provider outreach that will provide the appropriate information and resources to allow this to be as smooth implementation as possible.

Beneficiaries will receive up to three attempted calls from the contracted vendor to initiate the enrollment process into this program, allow time for questions/answers, and initiate the first delivery of the specialty drug needed. Beneficaries will also receive a letter at least 30 days prior to implementation via postal service notifying them of the policy change. This letter will include detailed information about how this could impact them and who to contact if additional information is needed.

Prescribers will be contacted to obtain a new prescription on the beneficiary's behalf approximately 15 days prior to the start of the program.

The specialty medication needed will be provided by mail order through one of the contracted specialty pharmacies. These pharmacies ship the medications directly to the site of administration (e.g., physician's office, beneficiary's home). The contracted vendor must provide beneficiaries, physicians and any other appropriate health care providers

access to clinical hemophilia, hepatitis C and IVIG specialists 24 hours a day, seven days a week through a toll-free telephone number. Calls will be responded to promptly and accurately.

Web announcements will be posted prior to and ~~at~~ during implementation on the Medicaid Pharmacy website with detailed Specialty Pharmacy Drug Program information and resources. Web education for prescribers will be a collaborative effort by the contracted vendor's account management, specialty pharmacy services personnel and the DHCFP. Additionally, a public workshop ~~will be~~was held o~~i~~n ~~November~~ December 2, 2020 where an overview ~~will be~~was provided and time for questions from anyone in the public.

The Medicaid Pharmacy website will be updated to include a section of the site dedicated to Specialty Pharmacy Drug Program services and resources. This site is available to the public.

Part IV: Program Operations

A. Beneficiary Information

Describe how beneficiaries will get information about the selective contracting program.

Nevada Medicaid beneficiaries that are identified as needing to transition to the Specialty Pharmacy Drug Program, will receive three phone call attempts from the contracted vendor to introduce and explain the program, answer questions and initiate the first delivery of the specialty drug.

Beneficiaries will receive a letter at least 30 days prior to implementation via postal service notifying them of the policy change and detailed information about how this could impact them and who to contact if additional information is needed. These letters will be distributed prior to the program implementation and on two separate dates.

The contracted vendor's Call Center will be available 24 hours a day, seven days a week through a toll-free telephone number.

A public workshop ~~will be scheduled for~~was held ~~November~~ December 2~~.~~, 2020, a public hearing is scheduled for ~~December~~ May 2~~5~~9, 2021~~0~~ where the SPA and MSM Chapter changes will be presented, and public information will be posted on the Medicaid Pharmacy website.

B. Individuals with Special Needs.

_x_ The State has special processes in place for persons with special needs (Please provide detail).

The contracted vendor has ensured the DHCFP that the selected pharmacies and treatment support staff have experience with the selected population. In addition, the Hemostasis and Thrombosis Center of Nevada (HTCNV), Nevada's federally recognized Hemophilia Treatment Center, will manage their current beneficiaries which are carved-out of the specialty pharmacy program.

The contracted vendor provides services to beneficiaries with special needs (i.e. non-English speaking, hearing impaired/disabled) via an interpreter or through a hearing impaired/disabled (TTY) line.

Section B – Waiver Cost-Effectiveness & Efficiency

Efficient and economic provision of covered care and services:

1. Provide a description of the State's efficient and economic provision of covered care and services.

Nevada's Specialty Pharmacy Drug Program will lock-in and require FFS beneficiaries and providers to acquire selected specialty medications by mail order through contracted specialty pharmacies. These pharmacies ship the medications directly to the site of administration (e.g., physician's office, beneficiary's home). The shipping occurs within 24-hours of ordering the medication. The State pays the specialty pharmacies based on pricing negotiated per contract.

The contracted vendor has identified that there are an estimated 3607~~7~~ (based on 2019 enrollment data) FFS beneficiaries, excluding the 17 beneficiaries served by HTCNV, that may be impacted by this waiver.

Monthly cost reports will be provided to the DHCFP by the Specialty Pharmacy contracted vendor that will include total drug spend, drug utilization and cost report for specialty drugs, top 10 high-cost specialty drugs, top five therapeutic classes by ingredient, top 25 pharmacies by ingredient cost and top 25 prescribers by ingredient cost.

The contracted vendor has provided DHCFP estimated annual savings of approximately $~~6,288,227~~1,651,901 creating a savings of $~~14~~,219~~735~~ per prescription.

2. Project the waiver expenditures for the upcoming waiver period.

Year 1 from: ~~7~~1/1/2021 to ~~12~~6/31/2022~~1~~

Trend rate from current expenditures (or historical figures): 5%

Projected pre-waiver cost:	$~~62,388,427~~59,987,635
Projected Waiver cost:	$58,538,489~~56,586,304~~
Difference:	$ 1,449,146~~5,802,124~~

Year 2 from: ~~7~~1/1/2022 to ~~6~~12/3~~0~~1/2023~~2~~

Trend rate from current expenditures (or historical figures): 5.05%

Projected pre-waiver cost: $63,017,011~~8,816,226~~
Projected Waiver cost: $61,494,683~~62,416,317~~
Difference: $ 1,522,328~~6,399,909~~

Year 3 (if applicable) from: 7~~1~~/1/2023 to 6~~12~~/30~~1~~/202~~43~~
(*For renewals, use trend rate from previous year and claims data from the CMS-64*)

Projected pre-waiver cost: $~~73,633,362~~67,428,202
Projected Waiver cost: $65,799,311~~66,785,459~~
Difference: $ 1,628,891~~6,847,903~~

Year 4 (if applicable) from: 7~~1~~/1/2024 to 6~~12~~/30~~1~~/2025~~4~~
(*For renewals, use trend rate from previous year and claims data from the CMS-64*)

Projected pre-waiver cost: $72,822,458~~9,524,031~~
Projected Waiver cost: $71,063,256~~2,128,296~~
Difference: $ 1,759,202~~7,395,735~~

Year 5 (if applicable) from: 7~~1~~/1/2025 to 6~~12~~/30~~1~~/2026~~5~~
(*For renewals, use trend rate from previous year and claims data from the CMS-64*)

Projected pre-waiver cost: $~~85,885,953~~78,648,255
Projected Waiver cost: $76,748,316~~7,898,560~~
Difference: $ 1,899,939~~7,987,393~~