Application for

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

June, 2012

v1.0

Table of Contents

Facesheet 3

Section A – Waiver Program Description 4

Part I: Program Overview

Tribal Consultation 4
Program Description 4
Waiver Services 4
A. Statutory Authority 5
B. Delivery Systems 5
C. Restriction of Freedom-of-Choice 5
D. Populations Affected by Waiver 6

Part II: Access, Provider Capacity and Utilization Standards

A. Timely Access Standards 7
B. Provider Capacity Standards 7
C. Utilization Standards 8

Part III: Quality

A. Quality Standards and Contract Monitoring 9
B. Coordination and Continuity-of-Care Standards 9

Part IV: Program Operations

A. Beneficiary Information 10
B. Individuals with Special Needs 10

Section B– Waiver Cost-Effectiveness and Efficiency 10

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

Face sheet

The **State** of **Oregon** 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 **Hemophilia program.**
(List each program name if the waiver authorizes more than one program.).

Type of request. This is:
☒ an initial request for new waiver. All sections are filled.
☐ a request to amend an existing waiver, which modifies Section/Par
☐ 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/renewal/amendment is requested for a period of ___5____ years beginning __1/1/18_____and ending___12/31/22____.

State Contact: The State contact person for this waiver is _**Jesse Anderson**_____and can be reached by telephone at (503)945-6958 ,or fax at(503)373-7689, or e-mail at jesse.anderson@state.o.us(List for each program)

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 (if additional space is needed, please supplement your answer with a Word attachment).

Per OHA Tribal consultation policy, Oregon Tribal entities were consulted in the submission of a pharmacy state plan on the changes required for the covered outpatient drug regulation during the February 22, 2017 "770" Health Cluster meeting. Further detailed discussions occurred during the May 24, 2017 "770" Health Cluster meeting. During subsequent discussions with CMS it was determined that Oregon should have a 1915(b)(4) waiver for the hemophilia specific contract.

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 (if additional space is needed, please supplement your answer with a Word attachment).

Currently OHA has a sole-source contract with OHSU Hemophilia Treatment Center (HTC), a 340B covered entity, to provide hemophilia factor and related blood products, and associated care management services to Medicaid clients. The contract came about through a competitive bid procurement process in 2010 (RFP #3052) and HTC was the only qualifying proposer. As a 340B covered entity, the HTC can only provide hemophilia factor to HTC patients. Currently there are approximately 45 Medicaid clients that have hemophilia and utilize HTC services.

Waiver Services: Please list all existing State Plan services the State will provide through this selective contracting waiver (if additional space is needed, please supplement your answer with a Word attachment).

Prescription medications-anti-hemophilia factor (AHF), medication management which includes comprehensive clinical support, and care management to Oregon's FFS Medicaid clients with hemophilia.

A. Statutory Authority

1.**Waiver Authority.** The State is seeking authority under the following subsection of 1915(b):
☒ **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) - Statewideness**
b. ☒ **Section 1902(a) (10) (B) - Comparability of Services**
c. ☒ **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
☐ is different than stipulated in the State Plan (please describe)

2.**Procurement**. The State will select the contractor in the following manner:
☒ **Competitive** procurement
☐ **Open** cooperative procurement
☐ **Sole source** procurement
☐ **Other** (please describe)

C. Restriction of Freedom of Choice

1.**Provider Limitations**.
☒ 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)

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 (if additional space is needed, please supplement your answer with a Word attachment).

All requirements for PA, quantity limits, FDA approved drugs, rebateable manufacturers would apply to any reimbursement made by the state for hemophilia factor as under state plan outpatient drug regulations.

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:

☒ Section 1931 Children and Related Populations
☒ Section 1931 Adults and Related Populations
☒ Blind/Disabled Adults and Related Populations
☒ Blind/Disabled Children and Related Populations
☒ Aged and Related Populations
☒ Foster Care Children
☒ 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
☒ Individuals residing in a nursing facility or ICF/MR
☒ Individuals enrolled in a managed care program
☐ Individuals participating in a HCBS Waiver program
☐ 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?

a. HTC must provide patients, physicians, and all other health care providers access to clinical hemophilia specialists 24 hours a day, seven days a week through a toll-free telephone number. Calls must responded to promptly and accurately at all times.
b. HTC must report on call center performance, including call wait times and the number of telephone encounters resolved with one call versus multiple calls. OHA monitors these reports. Call wait times average less than 30 seconds.
c. The HTC must turnaround all prescriptions within two business days. HTC must report delivery performance and OHA monitors these reports. Deliveries have been within 24 hours in at least 95% of cases each quarter. The HTC must also arrange for emergency delivery of anti-hemophilic clotting factor as needed.

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 (if additional space is needed, please supplement your answer with a Word attachment)?

HTC provides quarterly monitoring reports that include the following information: delivery statistics (portion sent within 24 hours by UPS/FedEx), call center performance (wait times, number of calls), telephone encounter data (the number of calls with medical staff before resolution), dosing compliance (portion within 4% variance), and claims summary data (identifying each prescriber's variance rate, the NDC and units provided to each client). This allows OHA to monitor to ensure contract goals are met.

In addition, OHA's agreement requires the HTC to provide a number of additional services. For example, the HTC is obligated to provide patients, physicians and all other health care provider access to clinical hemophilia specialists 24 hours a day, seven days a week, through a toll-free telephone number. They must also provide medically necessary home nursing and infusion services through home nursing visits up to 1.5 hours per week per patient. The HTC also must ensure sufficient product quantity and inventory to maintain adequate supply, with a range of assays, for ongoing and emergency client 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 additional space is needed, please supplement your answer with a Word attachment).

The HTC support staff, available by phone at all hours of all days, will arrange for emergency supplies of factor products when needed. In addition, the OHA's Pharmacy Call Center can override system edits as needed to allow the Medicaid beneficiary to access services through any enrolled pharmacy.

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 (if additional space is needed, please supplement your answer with a Word attachment).

   Oregon Medicaid has 840 enrolled pharmacies that supply Medicaid recipients with prescribed drugs statewide. The majority of Oregon hemophilia clients were seen by the HTC before the procurement process, a few others used specialty mail order companies, and a small number used local pharmacies. Additionally OHA's contracted Pharmacy Call Center can override an authorization for urgent situations or when the client has TPL or Medicare. If an authorization is denied the provider can call the Pharmacy call center with

any additional information that may warrant an override. TPL and Medicare coverage warrant an automatic approval for an override.

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 (if additional space is needed, please supplement your answer with a Word attachment).

Ninety percent of OHP clients are enrolled in a coordinated care organization, the remaining ten percent, access services through the fee-for-service delivery system The Oregon Health Plan has several mechanisms and reporting systems designed to monitor access in the fee-for-service delivery system and provide oversight of access in the managed care delivery system.

Fee-For-Service Access

Some of the methods we currently use to identify and resolve access issues for fee-for-service clients: Client Services Unit (CSU), Governor's Advocacy Office and OHP Ombudsman.

In addition, on a quarterly basis, CSU meets with the Governor's Advocacy Office and the OHP Ombudsman to discuss systemic issues, which are then taken to the HSD Program Unit to review and resolve.

However, this question is not applicable to this request as we are requesting this waiver in order to restrict use to the HTC that specializes in hemophilia drugs, medication management and clinical support protocols.

B. 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 ?

Oregon currently has 1,062,747 individuals enrolled in the Medicaid/CHIP, approximately 66,000 of those are fee-for-service and of those approximately 45 have hemophilia and utilize HTC services.

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 (if additional space is needed, please supplement your answer with a Word attachment).

The number of Medicaid recipients with hemophilia is low in Oregon and the HTC provider has ample capacity for additional enrollment. HTC is one of 12 federally funded regional hemophilia centers nationwide. As the regional core treatment center, HTC

collaborates with the other centers throughout the Western United States. HTC has seen increased clients (Medicaid and non Medicaid) in the last few years due general population movement to Oregon. If in any future date access becomes an issue OHA will provided the necessary treatments through any other enrolled pharmacy.

Part III: Quality

A. Quality Standards and Contract Monitoring

1. Describe the State's quality measurement standards specific to the selective contracting program (if additional space is needed, please supplement your answer with a Word attachment).
    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.
        ii. Take(s) corrective action if there is a failure to comply.

HTC provides quarterly monitoring reports that include the following information: enrollee data (number new active, active, pending and never started enrollees), delivery statistics (portion sent within 24 hours by UPS/FedEx), call center performance (wait times, number of calls), telephone encounter data (the number of calls with medical staff before resolution), dosing compliance (portion within 4% variance), inquiry and complaint statistics, and claims summary data (identifying each prescriber's variance rate, the NDC and units provided to each client). This allows OHA to monitor to ensure contract goals are met.

HTC must explain provide supplemental explanatory information upon request. If such information does not satisfy OHA's concerns, the OHA will issue a 30-day notice and demand for cure. If the issue is not cured, the OHA will terminate the contract and notify enrollees they may seek services from the enrolled provider of their choosing. Prior 30-day notice is not required and contract termination may be immediate if patient health or safety is endangered.

2. Describe the State's contract monitoring process specific to the selective contracting program (if additional space is needed, please supplement your answer with a Word attachment).
    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.
        ii. Take(s) corrective action if there is a failure to comply.

HTC provides quarterly monitoring reports that include the following information: enrollee data (number new active, active, pending and never started enrollees), delivery statistics (portion sent within 24 hours by UPS/FedEx), call center performance (wait times,

number of calls), telephone encounter data (the number of calls with medical staff before resolution), dosing compliance (portion within 4% variance), inquiry and complaint statistics, and claims summary data (identifying each prescriber's variance rate, the NDC and units provided to each client). This allows OHA to monitor to ensure contract goals are met.

HTC must explain provide supplemental explanatory information upon request. If such information does not satisfy OHA's concerns, the OHA will issue a 30-day notice and demand for cure. If the issue is not cured, the OHA will terminate the contract and notify enrollees they may seek services from the enrolled provider of their choosing. Prior 30-day notice is not required and contract termination may be immediate if patient health or safety is endangered.

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 (if additional space is needed, please supplement your answer with a Word attachment).

Before our HTC contract, we found the majority of Oregon hemophilia clients were already seen by the HTC. Recipients can keep their own physician and receive services through HTC. Additionally the Pharmacy Call Center can override the edit for urgent situations.

Part IV: Program Operations

A. Beneficiary Information

Describe how beneficiaries will get information about the selective contracting program (if additional space is needed, please supplement your answer with a Word attachment.

The HTC makes contact with clients identified as needing to transition their factor concentrate provider. The HTC will explain why a transition is necessary, introduce key personnel, explain procedures for ordering factor and provide daytime and after-hour contacts. The HTC will make repeated efforts by phone, and by mail or email as necessary.

B. Individuals with Special Needs.

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

The State Medicaid Agency has contracts with interpreters who speak or sign in all languages.

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 (if additional space is needed, please supplement your answer with a Word attachment).

Services will be provided efficiently through shipping that occurs within 24-hours of ordering and overall variance within 4% of prescribed.

OHA estimates annual savings of approximately $1.2M based on 340B ingredient pricing alone. This estimate includes consideration of lost rebate and the contracted cost of care management and dispensing costs. OHA expects additional savings through high quality care management and reduced variance.

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

Year 1 from 1/1/18 to 12/31/18

Trend rate from current expenditures (or historical figures): 3 %
Projected pre-waiver cost $6,233,551
Projected Waiver cost $4,986,840
Difference: -$1,246,710 (savings)

Year 2 from 1/1/19 to 12/31/19

Trend rate from current expenditures (or historical figures): 3%
Projected pre-waiver cost $6,429,627
Projected Waiver cost $5,143,701
Difference: -$1,285,925 (savings)

Year 3 (if applicable) from: 1/1/20 to 12/31/20
(*For renewals, use trend rate from previous year and claims data from the CMS-64*)

Projected pre-waiver cost $6,625,703
Projected Waiver cost $5,300,562
Difference: -$1,325,141 (savings)

Year 4 (if applicable) from 1/1/21 to 12/31/21
(*For renewals, use trend rate from previous year and claims data from the CMS-64*)

Projected pre-waiver cost $6,821,779
Projected Waiver cost $5,457,423
Difference: -$1,364,356 (savings)

Year 5 (if applicable) from 1/1/22 to 12/31/22
(*For renewals, use trend rate from previous year and claims data from the CMS-64*)

Projected pre-waiver cost $6,870,798
Projected Waiver cost $5,496,638
Difference: -$1,374,160 (savings)