

Renewal Request for the End-Stage Renal Disease Section 1115 Waiver

[Project Number 11-W-00237/5]

05/13/2020

Table of Contents

Section 1: Summary of the Request	3
Section 2: Historical Narrative	3
2.1 Original Objectives	5
Progress Toward Achievement of Objectives.....	5
2.3 Renewal Objectives	7
Section 3: Demonstration Components and Operations	7
3.1 Demonstration Area	7
3.2 Demonstration Timeframe	7
3.3 Demonstration Impact to Medicaid and CHIP.....	8
3.4 Projected Eligibility and Enrollment	8
3.5 Cost-sharing and Benefits	8
3.7 Premiums	8
3.8 Copayments, Coinsurance and Deductibles	8
3.9 Cost Sharing Justification	9
3.10 Cost Sharing Exemptions	9
3.11 Long-Term Services and Supports	9
Section 4: Changes Requested.....	9
Section 5: List of Proposed Waivers and Expenditure Authorities.....	10
Section 6: External Quality Review Organization (EQRO) Reports	10
Section 7: Financial Data.....	10
Section 8: Evaluation Report	11
Section 9: Public Comment Period	11
9.1 Summary of Public Comments	11
9.2 Tribal Consultation.....	11
9.3 State Response	12
Demonstration Administration.....	12
Appendix A: Long Public Notice.....	13
Appendix B: Abbreviated Public Notice.....	19
Appendix C: Tribal Consultation Public Notice	21
Attachment D: Draft Evaluation Design.....	22

Section 1: Summary of the Request

The ESRD §1115 Demonstration has ensured access to supplemental transplant coverage for a total of 760 unique enrollees since its inception in May 2014. Without access to the coverage provided by this demonstration, covered individuals might not have been able to access needed kidney transplant services and wraparound coverage. This §1115 Demonstration waiver renewal requests a continuation of the current authority to cover individuals with end-stage renal disease who meet the applicable eligibility criteria.

Section 2: Historical Narrative

Indiana's current End Stage Renal Disease (ESRD) program began in May 2014, when CMS approved an amendment to include former spend-down enrollees diagnosed with ESRD as a covered population within the Healthy Indiana Plan (HIP) §1115(a) Medicaid demonstration. ESRD enrollees are Medicare beneficiaries without any alternative means of access to supplemental health care coverage. By providing supplemental coverage, including costs associated with transplants, this waiver allows individuals to remain on transplant lists and thus retain access to kidney transplants.

In January 2015, CMS approved Indiana's HIP 2.0 demonstration, to which the State subsequently transitioned most of its former HIP enrollees. ESRD enrollees were the only population remaining in the original HIP demonstration. The demonstration continued to operate this way under a temporary extension until July 2016, when it was renewed and renamed "End-Stage Renal Disease §1115 Waiver."

Indiana's ESRD demonstration continues to provide coverage for individuals with ESRD that are not otherwise eligible for Medicaid coverage. There are currently two distinct eligibility groups enrolled that receive coverage through the ESRD §1115 authority:

Population 1 [Former Spend-Down Enrollees]: The first group includes individuals with income over 150 percent of the Federal Poverty Limit (FPL) who were enrolled in both Medicare and the State's Medicaid Spend-down program as of May 31, 2014 (the last day the State operated under 209(b) status). This population met the spend-down eligibility requirements in effect under the State's 209(b) rules as of May 31, 2014, and were not subject to an upper income limit. These enrollees would have lost access to supplemental ESRD coverage as a result of the State's transition to a 1634 state. These individuals are referred to as "former spend down enrollees" in this waiver renewal request.

Population 2 [New Enrollees]: In addition to transitioning former spend-down enrollees to the ESRD §1115 effective June 1, 2014, new enrollees were also permitted. However, the ESRD waiver applied an income limit of 300 percent FPL to this population. This income limit applies to all ESRD §1115 enrollees who were not enrolled in the Indiana spend-down program as of May 31, 2014. Such enrollees are referred to as "new enrollees" in this waiver request.

As of March 2020, there are 39 members enrolled in Population 1 and 286 members enrolled in Population 2.

To gain full Medicaid coverage through the ESRD §1115 demonstration, all enrolled individuals (regardless of population) must incur sufficient medical expenses to bring their income down to the Supplemental Security Income (SSI) federal benefit rate (FBR). All enrollees must repeat this same process each month in order to meet their respective ESRD liabilities.

In order to qualify for the ESRD demonstration, new enrollees must meet the following eligibility requirements:

- Enrollee has a current diagnosis of End-Stage Renal Disease;
- Enrollee is approved to receive Medicare part A and B;
- Enrollee has resources under \$2,250 for an individual, under \$3,000 for a couple;
- Enrollee is not institutionalized;
- Enrollee meets all non-financial Medicaid eligibility requirements; and
- Enrollee is not eligible for any other Medicaid category.

A summary of the ESRD eligibility criteria by population group is illustrated in Table 1 below.

Table 1: Summary of ESRD 1115 demonstration eligibility.

Group	Eligibility Criteria
<p>Population 1 – Former Spend Down Enrollees</p>	<ul style="list-style-type: none"> • On Medicaid before May 31, 2014 • Non-MAGI income is over 150% FPL, with no upper limit • Current diagnosis of End-Stage Renal Disease • Approved to receive Medicare part A and B • Resources under \$2,250 for an individual, under \$3,000 for a couple • Not institutionalized • Meet all non-financial Medicaid eligibility requirements • Not eligible for any other Medicaid
<p>Population 2 – New Enrollees</p>	<ul style="list-style-type: none"> • On Medicaid after May 31, 2014 • Non-MAGI income is between 150% and 300% FPL • Current diagnosis of End-Stage Renal Disease • Approved to receive Medicare part A and B • Resources under \$2,250 for an individual, under \$3,000 for a couple • Not institutionalized • Meet all non-financial Medicaid eligibility requirements • Not eligible for any other Medicaid

The ESRD demonstration currently provides Medicare-enrolled individuals, who are otherwise ineligible for Medicaid, with wraparound coverage, which includes supplemental coverage for kidney transplant services. The participants in the demonstration receive services through a fee-for-service (FFS) delivery system and once they meet their required ESRD liability are subject to the same cost-sharing as described in Indiana’s approved Medicaid state plan.

ESRD demonstration enrollees also receive access to Non-Emergency Medical Transportation (NEMT), in the form of an administrative activity or service to ensure non-emergency transportation to and from providers.

2.1 Original Objectives

The original objectives of this demonstration were to:

- 1) Increase overall coverage of low-income individuals with a diagnosis of ESRD; and
- 2) Ensure access to comprehensive coverage for low-income individuals with a diagnosis of ESRD and primary coverage through Medicare.

Progress Toward Achievement of Objectives

1) Increase overall coverage of low-income individuals with a diagnosis of ESRD

From May 1, 2014 through March 31, 2020, there is a total of 760 unique ESRD waiver enrollees ever enrolled in this program. Total annual enrollment of unique enrollees has decreased by approximately 20% over the course of the waiver period, however the number of new individuals enrolled has remained consistent, so this decrease represents program attrition, not a lack of program access for new enrollees. A summary of annual enrollment is presented in Table 2.

Table 2: ESRD Demonstration Enrollment by Year, 2014 – 2020.

Population	May 1- Dec 31 2014	2015	2016	2017	2018	2019	Q1 2020
Demonstration Population 1 – Former Spend Down Enrollees	37	40	42	42	42	42	39
Demonstration Population 2 – New Enrollees	372	354	354	357	339	314	286
Total Number of Demonstration Enrollees	409	394	396	399	381	356	325

2) Ensure access to comprehensive coverage for low-income individuals with a diagnosis of ESRD and primary coverage through Medicare.

A summary of health care utilization among ESRD enrollees from 2014 through 2020 is presented in Table 3. This table shows the number of enrollees with various claim types per year and the claims total for these expenditure categories. The total number of enrollees per year with transplant claims has increased over the course of the program and the number of enrollees with dialysis claims has decreased over the course of the program. This is an expected result of providing supplemental coverage to ensure access to transplants for this population. Note that enrollees that receive a transplant will continue to have follow-up transplant claims, and transplant claim in any year does not indicate that a transplant procedure was performed for that enrollee in the year.

Table 3: ESRD Health Care Utilization May 1, 2014 – December 31, 2019

Claims Category	May 1- Dec. 31, 2014		2015		2016		2017		2018		2019	
	Unique Enrollment	Expenditures	Unique Enrollment	Expenditures	Unique Enrollment	Expenditures	Unique Enrollment	Expenditures	Unique Enrollment	Expenditures	Unique Enrollment	Expenditures
Transplants	51	\$27,162	62	\$64,186	55	\$56,824	67	\$54,337	80	\$59,711	82	\$60,202
Dialysis	442	\$679,031	418	\$718,374	370	\$553,834	379	\$575,545	380	\$779,804	353	\$735,523
Dental	72	\$26,111	64	\$19,039	63	\$15,887	63	\$24,454	71	\$19,036	83	\$30,163
Home health	7	\$ 52,409	9	\$51,257	18	\$179,458	16	\$160,623	13	\$167,266	15	\$113,437
Inpatient	169	\$213,372	205	\$205,632	200	\$199,902	201	\$283,049	216	\$506,021	187	\$331,613
Long-term care	26	\$331,388	35	\$747,771	33	\$688,114	33	\$751,604	33	\$869,719	36	\$977,252
Outpatient	440	\$375,108	424	\$287,145	387	\$272,150	395	\$209,839	401	\$258,306	381	\$320,050
Pharmacy	126	\$36,817	110	\$12,328	102	\$11,482	101	\$3,892	106	\$17,990	103	\$30,725
Physician	461	\$334,109	430	\$526,549	401	\$581,406	414	\$544,408	409	\$537,636	395	\$587,375
Totals:	409*	\$2,075,507	394*	\$2,632,280	396*	\$2,559,056	399*	\$2,607,750	381*	\$3,215,489	356*	\$3,186,340

**Total unique enrollee count for the demonstration year*

2.3 Renewal Objectives

The current objectives of this demonstration are to:

- 1) Ensure that ESRD §1115 waiver enrollees maintain access to kidney transplant waiting lists.
- 2) Ensure that ESRD §1115 waiver enrollees have access kidney to transplants.
- 3) Ensure that there is continued access to the program for new enrollees.
- 4) Promote and increase Medicare Advantage (MA) awareness among ESRD waiver enrollees.

The hypotheses for the current objectives are:

- 1) ESRD §1115 waiver enrollees will maintain access to kidney transplant waiting lists.
- 2) ESRD §1115 waiver enrollees will have access to kidney transplants and the supplemental coverage needed to ultimately end their ESRD diagnosis and increase access to a broader market of health coverage.
- 3) The ESRD §1115 waiver demonstration will enroll newly-eligible individuals.
- 4) The ESRD §1115 waiver demonstration will enroll individuals who are eligible through Medicare/Medicaid spend-down.
- 5) The ESRD §1115 waiver will promote awareness and enrollment of ESRD waiver recipients in Medicare Advantage (MA) plans.

To test these hypotheses, the ESRD §1115 waiver will utilize the following evaluation measures:

- Track waiver enrollment and enrollment trends over the course of the demonstration
- Track waiver enrollees who are on the transplant list as well as those who are not.
- Track how many individuals on the waiver receive a kidney transplant.
- Track how many enrollees become ineligible for the waiver due to no longer having an ESRD diagnosis.
- Track how many newly-eligible enrollees gain coverage under the waiver.
- Track total and average waiver spend-down totals for ESRD waiver recipients and the frequency with which ESRD waiver liability is met annually
- Track total expenditures associated with ESRD waiver enrollees.
- Track specific Medicare enrollment type (Fee-for-service, MA, Medigap, etc.) for ESRD waiver enrollees.

A draft waiver evaluation design is included with this request as "Attachment D"

Section 3: Demonstration Components and Operations

The ESRD §1115 extension will operate in alignment with the following parameters:

3.1 Demonstration Area

This demonstration will continue apply to eligible individuals across the state.

3.2 Demonstration Timeframe

The new demonstration renewal period that the State seeks through this application is January 1, 2021 through December 31, 2025.

3.3 Demonstration Impact to Medicaid and CHIP

This demonstration will not impact or modify components of Indiana’s Medicaid or CHIP programs outside of eligibility or cost-sharing for individuals eligible under the waiver.

3.4 Projected Eligibility and Enrollment

The ESRD §1115 is projected to cover approximately 300 individuals on a monthly basis over the course the five-year waiver period. There are no enrollment limits for this demonstration.

3.5 Cost-sharing and Benefits

This demonstration does not propose any changes to cost-sharing. Individuals eligible under this demonstration will continue to be eligible for Medicaid state plan benefits after they meet their ESRD liability, a cost-sharing methodology described in Section 2.9.

Table 4: ESRD Benefit Package Summary.

Eligibility Group	Benefit Package
Former Spend-Down Enrollees	Full State Plan – Package A
New Enrollees	

ESRD §1115 enrollees will be eligible for all medically necessary Medicaid covered services after meeting an ESRD liability. The liability will be calculated using spend-down methodology based on incurred medical costs. Individuals who incur medical expenses that bring their income down to the Supplemental Security Income (SSI) federal benefit rate (FBR) will not incur any additional costs subject to the ESRD liability, but will have Medicaid State Plan cost-sharing as described in Section 3.8.

3.7 Premiums

This demonstration does not impose premiums on enrollees.

3.8 Copayments, Coinsurance and Deductibles

As illustrated by Table 5, copayments within the ESRD demonstration will be the same as the copayment amounts in the state plan.

Table 5: ESRD Copayment Amounts.

Service	Copayment Amount	
Transportation	\$0.50 each one-way trip	Transportation services that pay \$10 or less
	\$1 each one-way trip	Transportation services that pay \$10.01 to \$50
	\$2 each one-way trip	Transportation services that pay \$50.01 or more
Pharmacy	\$3	
Non-Emergency Use of the ED	\$3	

Outside of the required ESRD liability, ESRD §1115 enrollees will not spend more than 5 percent of their household income on state plan cost-sharing requirements.

3.9 Cost Sharing Justification

This demonstration preserves the benefits and cost-sharing structure this population would have experienced as of May 31, 2014 when the State operated under 209(b) authority. The demonstration will provide supplemental health insurance coverage to individuals above 150 percent FPL who are not eligible for comparable supplemental coverage and may otherwise be at risk for removal from kidney transplant wait lists. To prevent removal from transplant lists and support access to coverage, this demonstration will provide supplemental coverage using State spend-down rules in place on May 31, 2014.

3.10 Cost Sharing Exemptions

No individuals enrolled under the waiver will be exempt from an ESRD liability. This is in alignment with the spend-down methodology authorized by CMS when Indiana was a 209(b) state, and was subsequently extended to certain ESRD enrollees in May 2014 and November 2014. However, individuals will not be subject to state plan copayments once they have reached the 5 percent of household income limit.

3.11 Long-Term Services and Supports

Individuals eligible under this waiver do not qualify for long-term services and supports through either home and community-based service waivers or while institutionalized in a nursing facility. This was first described in the State's original §1115 expenditure authority authorized in May 2014 and extended in November 2014. Consequently, post-eligibility treatment of income and spousal impoverishment rules are not applicable.¹ Long-term care services are covered for non-institutionalized individuals.

Section 4: Changes Requested

Indiana's ESRD program seeks to continue operations consistent with the current program with the minor changes noted below:

- 1) In an effort to help promote access to program, the State seeks to increase asset limits from \$1,500 to \$2,250 for individuals and increasing asset limits from \$2,000 to \$3,000 for couples.
- 2) The program also seeks one primary modification around communication to beneficiaries. Beginning in January 2021, as required by the *21st Century Cures Act of 2016*, all ESRD beneficiaries will have the option to enroll in a Medicare Advantage (MA) plan. MA is positioned to provide ESRD beneficiaries with potentially preferable coverage that is more comprehensive and affordable compared to traditional FFS Medicare, which lacks MA's maximum out-of-pocket limit for consumers, supplemental benefits, and ability to coordinate care. Due to the change in access to MA for individuals with ESRD, the State will notify members of this new enrollment opportunity and will coordinate with the State Health Insurance Assistance Program (SHIP) to ensure members who wish to enroll in MA have the assistance necessary for that transition. Enrollment in MA will not impact an individual's eligibility for the ESRD 1115 waiver.

¹ ESRD Individuals that become institutionalized may qualify for Medicaid with a patient liability but are no longer enrolled in the ESRD program with the separate ESRD liability.

Section 5: List of Proposed Waivers and Expenditure Authorities

The state requests continuation of the following waivers and expenditure authorities over the course of the extension.

1) Amount, Duration and Scope of Services – Section 1902(a)(10)(B)

To the extent necessary to enable the State to provide State Plan benefits only after an individual meets an ESRD liability, calculated using spend down methodologies.

2) Cost-Sharing Requirements – Section 1902(a)(14) related to provisions in section 1916

To the extent necessary to enable the State to impose a spend-down methodology based on incurred medical costs. Individuals who incur medical expenses that bring their income to the Supplemental Security Income (SSI) federal benefit rate (FBR) will have no further incurred costs subject to the ESRD liability.

3) Comparability – Section 1902(a)(17)

To the extent necessary to enable the State to apply a spend-down methodology based on incurred medical costs.

Section 6: External Quality Review Organization (EQRO) Reports

Indiana’s ESRD program has covered only a fraction of one percent of Indiana Medicaid members since its inception in 2014 through the present, and correspondingly, is not assigned specific evaluation from External Quality Review Organizations. The program is, however, evaluated and monitored by FSSA, and a summary is presented within each quarterly report, annual report and waiver renewal application. The most recent evaluation data is presented in Section 6 of this waiver renewal application.

Section 7: Financial Data

The State contracted Milliman to conduct a budget neutrality analysis and provide historical and projected expenditures for the ESRD demonstration. As illustrated by Table 6, Table 7 and Table 8, the ESRD demonstration remains budget neutral. The budget neutrality analysis is posted for review concurrently with this renewal request.

Table 6: Historical ESRD Expenditures, 2018.

TOTAL EXPENDITURES	\$1,460,202
ELIGIBLE MEMBER MONTHS	2,805
PMPM COST	\$520.57

Table 7: Projected ESRD Expenditures Without Waiver Authority, 2021 – 2025.

ESRD MEG 1									
Eligible Member Months	n.a.	n.a.	2,805	2,805	2,805	2,805	2,805	2,805	
PMPM Cost	4.6%	36	\$521	\$596	\$623	\$652	\$682	\$713	
Total Expenditure				\$1,671,135	\$1,748,020	\$1,828,439	\$1,912,561	\$2,000,526	\$9,160,681

Table 8: Projected ESRD Expenditures With Waiver Authority, 2021 – 2025.

ESRD MEG 1									
Eligible Member Months	n/a	n/a	2,805	2,805	2,805	2,805	2,805	2,805	
PMPM Cost	4.6%	36	\$521	\$596	\$623	\$652	\$682	\$713	
Total Expenditure				\$1,671,135	\$1,748,020	\$1,828,439	\$1,912,561	\$2,000,526	\$9,160,681

Section 8: Evaluation Report

The evaluation of the ESRD demonstration was completed by FSSA staff in alignment with the approved evaluation design available at <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/in/esrd/in-esrd-final-eval-dsgn-03222017.pdf>. This evaluation report is posted for review concurrently with this extension request.

Section 9: Public Comment Period

The Indiana Family and Social Services Administration (FSSA) is holding a 30-day public comment period for this waiver from May 13th, 2020 through June 12th, 2020. Hearings will be held virtually on May 19th and May 20th per the information contained in the public notices included as Attachments A and B.

9.1 Summary of Public Comments

Following completion of the public comment period, a summary of all public comments received will be included in this request.

9.2 Tribal Consultation

The Medical Director of the Pokagon Band of Potawatomi was notified in writing on March 4, 2020 of the development of the waiver application and asked to submit comments or questions directly to FSSA by May 4, 2020. A copy of the correspondence is included within Attachment C. FSSA provided an opportunity for an in-person meeting to discuss the waiver and Tribal impact. FSSA received no response or comments in response to the notice of Tribal comment period.

9.3 State Response

Following the completion of the comment period a response to received public comments will be included in this request.

Demonstration Administration

Name and Title: Angela Todd, State Program Director

Organization: Indiana Office of Medicaid Policy and Planning (OMPP)

Telephone Number: 317-234-803

Email Address: angela.todd@fssa.in.gov

Appendix A: Long Public Notice

OFFICE OF THE SECRETARY OF FAMILY AND SOCIAL SERVICES ADMINISTRATION

NOTICE OF PUBLIC COMMENT PERIOD TO EXTEND THE END-STAGE RENAL DISEASE S1115 DEMONSTRATION

In accordance with 42 CFR §431.408(a)(2)(ii), the Indiana Family and Social Services Administration (FSSA) will be holding public hearings on a proposed extension of the End Stage Renal Disease (ESRD) Section 1115 Medicaid demonstration that will be submitted to the Centers for Medicare and Medicaid Services (CMS).

This notice serves to open the 30-day public comment period, which closes **06/12/2020**. In addition to the 30-day public comment period in which the public will be able to provide written comments, FSSA will host public hearings in which the public may provide oral comments. Due to CDC COVID-19 social distancing recommendations, these meetings will be virtual only. Visit <https://www.in.gov/fssa/5537.htm> for the most up to date information regarding the public hearings. Hearings will be held as follows:

1. VIRTUAL MEETING

Tuesday, 05/19/2020, 1pm-2:30pm

To provide oral comments, access WebEx meeting:

Online: <https://indiana.webex.com/indiana/j.php?MTID=m4a78c124ee8e153c0ff5722f104c4dc7>

Password: 432H8GpusJi

One can also access online by going to <https://www.in.gov/fssa/5537.htm> and clicking link to WebEx meeting and entering the password

Call-in: Dial: 1-240-454-0887; Meeting ID (access code): 475 620 522

To post written comments online, login to Adobe Connect:

<https://Indiana.AdobeConnect.com/ompp>

2. VIRTUAL MEETING

Wednesday, 05/20/2020, 1pm-2:30pm

To provide oral comments, access WebEx meeting:

Online:

<https://indiana.webex.com/indiana/j.php?MTID=m71c4353e84ab6a552c014330cd0795a6>

Password: YGh9G5p7W52

One can also access online by going to <https://www.in.gov/fssa/5537.htm> and clicking link to WebEx meeting and entering the password

Call-in: Dial: 1-240-454-0887; Meeting ID (access code): 470 049 012

To post written comments online, login to Adobe Connect:

<https://Indiana.AdobeConnect.com/ompp>

Prior to finalizing the proposed ESRD demonstration, FSSA will consider all written and verbal public comments received. The comments will be summarized and addressed in the final version to be submitted to CMS.

EXTENSION PROPOSAL SUMMARY AND OBJECTIVES

The ESRD demonstration has been a feature of Indiana's Medicaid program since 2014. The current approval to operate the ESRD demonstration expires December 31, 2020. Through this submission, FSSA is seeking a five-year extension of the ESRD demonstration with two primary changes:

- 1) In an effort to help promote access to program, the State seeks to increase asset limits from \$1,500 to \$2,250 for individuals, and increasing asset limits from \$2,000 to \$3,000 for couples.
- 2) The program also seeks a modification around communication to beneficiaries. Beginning in January 2021, as required by the 21st Century Cures Act of 2016, all ESRD beneficiaries will have the option to enroll in Medicare Advantage (MA) plan. MA is positioned to provide ESRD beneficiaries with better coverage compared to Traditional FFS Medicare due to its maximum out-of-pocket limit for consumers, supplemental benefits, and ability to coordinate care. Due to the change in MA covering individuals, the State will notify members of this new enrollment opportunity and will coordinate with the State Health Insurance Assistance Program (SHIP) to ensure members who wish to enroll in MA have the needed assistance. Enrollment in MA will not impact an individual's eligibility for the ESRD §1115 waiver.

BENEFICIARIES & ELIGIBILITY

To gain full coverage under the ESRD §1115, each month all enrolled individuals, regardless of the enrollment dates, must incur medical expenses which bring their income to the Supplemental Security Income (SSI) federal benefit rate (FBR) by meeting their ESRD liability.

In order to qualify for the ESRD demonstration, new enrollees must meet the following eligibility requirements:

- Enrollee has a current diagnosis of End-Stage Renal Disease,
- Enrollee is approved to receive Medicare part A and B,
- Enrollee has resources under \$2,250 for an individual, under \$3,000 for a couple,
- Enrollee is not institutionalized,
- Enrollee meets all non-financial Medicaid eligibility requirements, and
- Enrollee is not eligible for any other Medicaid category.

A summary of the ESRD eligibility criteria by population group is illustrated in Table 1 below:

Table 1. Summary of ESRD 1115 demonstration eligibility.

Group	Eligibility Criteria
Population 1: Former Spend Down Enrollees	<ul style="list-style-type: none"> • Enrolled in Medicaid spend-down program before May 31, 2014 • Non-MAGI income is over 150% FPL, with no upper limit • Current diagnosis of End-Stage Renal Disease • Approved to receive Medicare part A and B • Resources under \$2,250 for an individual, under \$3,000 for a couple • Not institutionalized • Meet all non-financial Medicaid eligibility requirements • Not eligible for any other Medicaid
Population 2: New Enrollees	<ul style="list-style-type: none"> • On Medicaid after May 31, 2014 • Non-MAGI income is between 150% and 300% FPL • Current diagnosis of End-Stage Renal Disease • Approved to receive Medicare part A and B • Resources under \$2,250 for an individual, under \$3,000 for a couple • Not institutionalized • Meet all non-financial Medicaid eligibility requirements • Not eligible for any other Medicaid

ENROLLMENT & FISCAL PROJECTIONS

The ESRD demonstration extension will have no impact on expected annual Medicaid enrollment as the program has maintained no more than four hundred and forty enrollees since 2014. Further, it is expected to be budget neutral as outlined within the two tables below.

Table 2. Projected ESRD Expenditures Without Waiver Authority, 2021 – 2025.

	Historical	2021	2022	2023	2024	2025	Total
Eligible Member Months	2,805	2,805	2,805	2,805	2,805	2,805	
PMPM Cost	\$521	\$596	\$623	\$652	\$682	\$713	
Total Expenditure		\$1,671,135	\$1,748,020	\$1,828,439	\$1,912,561	\$2,000,526	\$9,160,681

Table 3. Projected ESRD Expenditures With Waiver Authority, 2021 – 2025.

	Historical	2021	2022	2023	2024	2025	Total
Eligible Member Months	2,805	2,805	2,805	2,805	2,805	2,805	
PMPM Cost	\$521	\$596	\$623	\$652	\$682	\$713	
Total Expenditure		\$1,671,135	\$1,748,020	\$1,828,439	\$1,912,561	\$2,000,526	\$9,160,681

BENEFITS, COST SHARING, AND DELIVERY SYSTEM

This demonstration does not propose any changes to cost-sharing. Individuals eligible under this demonstration will continue to be eligible for State Plan benefits after they meet their ESRD liability.

Table 4. ESRD Benefit Package Summary.

Eligibility Group	Benefit Package
Former Spend-Down Enrollees	Full State Plan – Package A
New Enrollees	

ESRD §1115 enrollees will be eligible for all medically necessary Medicaid covered services after meeting an ESRD liability. The liability will be calculated using spend-down methodology based on incurred medical costs. Individuals who incur medical expenses that bring their income down to the Supplemental Security Income (SSI) federal benefit rate (FBR) will have no further incurred costs subject to the ESRD liability, but will have some cost sharing as described below.

As illustrated by Table 3, copayments within the ESRD demonstration will be the same as the copayment amounts with the State Plan.

Table 5. ESRD Copayment Amounts.

Service	Copayment Amount	
Transportation	\$0.50 each one-way trip	Transportation services that pay \$10 or less
	\$1 each one-way trip	Transportation services that pay \$10.01 to \$50
	\$2 each one-way trip	Transportation services that pay \$50.01 or more
Pharmacy	\$3	
Non-Emergency Use of the ED	\$3	

Outside of the required ESRD liability, ESRD §1115 enrollees will not spend more than 5 percent of their household income on state plan cost sharing requirements. ESRD enrollees are not subject to premium payments.

HYPOTHESES & EVALUATION

Between May 2014 and March 2020, the ESRD demonstration ensured coverage to 760 unique enrollees, covering on average approximately 400 unique enrollees per year. Enrollment has slightly declined over the course of the program but there continues to be comparable new enrollments (approximately 10 per quarter). The program has allowed individuals with end-stage renal disease who do not have another source of supplemental coverage the ability to remain on transplants lists and it provides comprehensive coverage for enrollees before during and after transplant.

Through the ESRD demonstration enrollees access the full range of Medicaid State Plan benefits including dialysis services needed to maintain their condition. The ESRD program continues to meet the goals and objectives as established at the onset of this demonstration.

Table 6. ESRD Health Care Utilization May 1, 2014 – December 31, 2019

Category	May 1- Dec. 31, 2014		2015		2016		2017		2018		2019	
	Unique Enrollee Count	Expenditures	Unique Enrollee Count	Expenditures	Unique Enrollee Count	Expenditures	Unique Enrollee Count	Expenditures	Unique Enrollee Count	Expenditures	Unique Enrollee Count	Expenditures
Transplants	51	\$ 27,162	62	\$ 64,186	55	\$ 56,824	67	\$ 54,337	80	\$ 59,711	82	\$ 60,202
Dialysis	442	\$ 679,031	418	\$ 718,374	370	\$ 553,834	379	\$ 575,545	380	\$ 779,804	353	\$ 735,523
Dental	72	\$ 26,111	64	\$ 19,039	63	\$ 15,887	63	\$ 24,454	71	\$ 19,036	83	\$ 30,163
Home health	7	\$ 52,409	9	\$ 51,257	18	\$ 179,458	16	\$ 160,623	13	\$ 167,266	15	\$ 113,437
Inpatient	169	\$ 213,372	205	\$ 205,632	200	\$ 199,902	201	\$ 283,049	216	\$ 506,021	187	\$ 331,613
Long term care	26	\$ 331,388	35	\$ 747,771	33	\$ 688,114	33	\$ 751,604	33	\$ 869,719	36	\$ 977,252
Outpatient	440	\$ 375,108	424	\$ 287,145	387	\$ 272,150	395	\$ 209,839	401	\$ 258,306	381	\$ 320,050
Pharmacy	126	\$ 36,817	110	\$ 12,328	102	\$ 11,482	101	\$ 3,892	106	\$ 17,990	103	\$ 30,725
Physician	461	\$ 334,109	430	\$ 526,549	401	\$ 581,406	414	\$ 544,408	409	\$ 537,636	395	\$ 587,375
Total	409*	\$ 2,075,507	394*	\$ 2,632,280	396*	\$ 2,559,056	399*	\$ 2,607,750	381*	\$ 3,215,489	356*	\$ 3,186,340

*Total unique enrollee count for the demonstration year

The current objectives of this demonstration are to:

- 1) Ensure that ESRD §1115 waiver enrollees maintain access to kidney transplant waiting lists.
- 2) Ensure that ESRD §1115 waiver enrollees have access kidney to transplants.
- 3) Ensure that individuals eligible for the ESRD demonstration through Medicare/Medicaid spend-down have access to the program.

The hypotheses for the current objectives are:

- 4) ESRD §1115 waiver enrollees will maintain access to kidney transplant waiting lists.
- 5) ESRD §1115 waiver enrollees will access kidney transplants, ending their diagnosis of ESRD and increasing their access to alternative forms of health insurance coverage.
- 6) The ESRD §1115 waiver demonstration will enroll individuals who are eligible through Medicare/Medicaid spend-down.

WAIVER & EXPENDITURE AUTHORITY

As specified in the ESRD demonstration extension, the requested waivers include:

1. Amount, Duration and Scope of Services – Section 1902(a)(10)(B)
To the extent necessary to enable the State to provide state plan benefits only after an individual meets an ESRD liability, calculated using spend-down methodologies.
2. Cost-Sharing Requirements – Section 1902(a)(14) related to provisions in section 1916
To the extent necessary to enable the State to impose a spend-down methodology based on incurred medical costs. Individuals who incur medical expenses that bring their income to the Supplemental Security Income (SSI) federal benefit rate (FBR) will have no further incurred costs subject to the ESRD liability.
3. Comparability – Section 1902(a)(17)
To the extent necessary to enable the State to apply a spend-down methodology based on incurred medical costs.

REVIEW OF DOCUMENTS & SUBMISSION OF COMMENTS

All information regarding the submission, including the public notice, the ESRD demonstration extension, and other documentation regarding the proposal are available for public review at the FSSA, Office of

General Counsel, 402 W. Washington Street, Room W451, Indianapolis, Indiana 46204. The full public notice and ESRD demonstration documents are also available to be viewed online at <https://www.in.gov/fssa/5537.htm>

Written comments may be sent to the FSSA via mail at 402 West Washington Street, Room W374, Indianapolis, Indiana 46204, Attention: Andrew Bean or via electronic mail at Andrew.Bean@fssa.in.gov through **06/12/2020** at 5:00 pm.

Appendix B: Abbreviated Public Notice

**OFFICE OF THE SECRETARY OF FAMILY AND SOCIAL SERVICES
ADMINISTRATION
NOTICE OF PUBLIC HEARING**

In accordance with 42 CFR §431.408(a)(2)(ii), the Indiana Family and Social Services Administration (FSSA) will be holding public hearings on a proposed extension of the End Stage Renal Disease (ESRD) Section 1115 Medicaid demonstration that will be submitted to the Centers for Medicare and Medicaid Services (CMS). The ESRD demonstration has been a feature of Indiana's Medicaid program since 2014. The current approval to operate the ESRD demonstration expires December 31, 2020. Through this submission, FSSA is seeking a five-year extension of the ESRD demonstration with two primary changes.

- 1) In an effort to help promote access to program, the State seeks to increase asset limits from \$1,500 to \$2,250 for individuals, and increasing asset limits from \$2,000 to \$3,000 for couples.
- 2) The program also seeks a modification around communication to beneficiaries. Beginning in January 2021, as required by the 21st Century Cures Act of 2016, all ESRD beneficiaries will have the option to enroll in Medicare Advantage (MA). MA is positioned to provide ESRD beneficiaries with better coverage compared to Traditional FFS Medicare due to its maximum out-of-pocket limit for consumers, supplemental benefits, and ability to coordinate care. Due to the change in MA covering individuals, the State will notify members of this new enrollment opportunity and will coordinate with the State Health Insurance Assistance Program (SHIP) to ensure members who wish to enroll in MA have the needed assistance. Enrollment in MA will not impact an individual's eligibility for the ESRD 1115 waiver.

This notice serves to open the 30-day public comment period, which closes **06/12/2020**. In addition to the 30-day public comment period in which the public will be able to provide written comments, FSSA will host public hearings in which the public may provide oral comments and post written comments. Due to the current state of emergency present at a state and federal level and CDC COVID-19 social distancing recommendations, these meetings will be virtual only. Visit <https://www.in.gov/fssa/5537.htm> for the most up to date information regarding the public hearings. Hearings will be held as follows:

3. VIRTUAL MEETING

Tuesday, 05/19/2020, 1pm-2:30pm

To provide oral comments, access WebEx meeting:

Online: <https://indiana.webex.com/indiana/j.php?MTID=m4a78c124ee8e153c0ff5722f104c4dc7>
Password: 432H8GpusJi

One can also access online by going to <https://www.in.gov/fssa/5537.htm> and clicking link to WebEx meeting and entering the password

Call-in: Dial: 1-240-454-0887; Meeting ID (access code): 475 620 522

To post written comments online, login to Adobe Connect:

<https://Indiana.AdobeConnect.com/ompp>

4. VIRTUAL MEETING

Wednesday, 05/20/2020, 1pm-2:30pm

To provide oral comments, access WebEx meeting:

Online: <https://indiana.webex.com/indiana/j.php?MTID=m71c4353e84ab6a552c014330cd0795a6>

Password: YGh9G5p7W52

One can also access online by going to <https://www.in.gov/fssa/5537.htm> and clicking link to WebEx meeting and entering the password

Call-in: Dial: 1-240-454-0887; Meeting ID (access code): 470 049 012

To post written comments online, login to Adobe Connect:

<https://Indiana.AdobeConnect.com/ompp>

The full Public Notice and ESRD demonstration documents are available to be viewed online at <https://www.in.gov/fssa/5537.htm>.

Written comments may be sent to the FSSA via mail at 402 West Washington Street, Room W374, Indianapolis, Indiana 46204, Attention: Andrew Bean or via electronic mail to Andrew.Bean@fssa.in.gov through **06/12/2020** at 5:00 pm.

Prior to finalizing the proposed ESRD demonstration, FSSA will consider all written and verbal public comments received. The comments will be summarized and addressed in the final version to be submitted to CMS.

Appendix C: Tribal Consultation Public Notice



Eric Holcomb, Governor
State of Indiana

Office of Medicaid Policy and Planning
MS 07, 402 W. WASHINGTON STREET, ROOM W382
INDIANAPOLIS, IN 46204-2739

March 4, 2020

Matt Clay
Medical Director
Pokagon Band of Potawatomi Indians
57392 M-51 South
Dowagiac, MI 49047

RE: Public Comment for End Stage Renal Disease (ESRD) §1115 Renewal

Dear Mr. Clay:

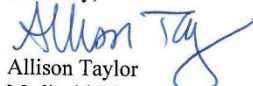
In May 2020, the Indiana Family and Social Service Administration (FSSA) intends to submit a renewal of its End Stage Renal Disease (ESRD) §1115 demonstration waiver to the Centers for Medicare and Medicaid Services (CMS) for consideration.

The 60-day notice and comment period will run from March 4, 2020 to May 4, 2020. The 30-day comment period will run from March 4, 2020 to April 3, 2020. Comments may be emailed to Amy.Owens@fssa.IN.gov or mailed to the address below:

Family and Social Services Administration, Office of Medicaid Policy and Planning
Attention: Amy Owens, Federal Relations Lead
402 W. Washington St., Room W374
Indianapolis, IN 46204

Please see the enclosed documentation, which provides additional details on the proposed revision. If you would like additional information or have any questions about the ESRD Waiver, please contact Amy Owens at Amy.Owens@fssa.IN.gov.

Sincerely,


Allison Taylor
Medicaid Director

Enclosure

cc: Matthew Wesaw, Chairman, Pokagon Band of Potawatomi Indians

www.IN.gov/fssa
Equal Opportunity/Affirmative Action Employer



Attachment D: Draft Evaluation Design

Evaluation Design:
End-Stage Renal Disease (ESRD) §1115
Demonstration Waiver

[Project Number 11-W-00237/5]

Indiana Family and Social Services Administration
Office of Medicaid Policy and Planning
May 13, 2020



**DRAFT EVALUATION DESIGN:
END-STAGE RENAL DISEASE (ESRD)
§1115 DEMONSTRATION WAIVER**

Introduction:

The Indiana End-Stage Renal Disease (ESRD) §1115 demonstration waiver has ensured critical access to supplemental wraparound coverage for Medicare-enrolled individuals with ESRD who would otherwise be ineligible for Medicaid coverage and would not qualify for other supplemental benefits such as Medicare Advantage (MA) plans, federal marketplace participation, or Medigap policies. Without supplemental health benefits, these individuals are at increased risk of being removed from transplant waiting lists. Through the ESRD §1115 waiver, demonstration enrollees have been able to access kidney transplants and related services, something which would be difficult to accomplish otherwise absent access to other supplemental benefits.

The objectives of the current ESRD §1115 demonstration are to:

- 1) Ensure that ESRD §1115 waiver enrollees maintain access to kidney transplant waiting lists.
- 2) Ensure that ESRD §1115 waiver enrollees have access kidney to transplants.
- 3) Ensure that there is continued access to the program for new enrollees.
- 4) Promote and increase Medicare Advantage (MA) awareness among ESRD waiver enrollees.

The State of Indiana respectfully submits this Draft Evaluation Design for the End-Stage Renal Disease (ESRD) §1115 Demonstration Waiver.

Background:

The §1115 End Stage Renal Disease (ESRD) demonstration waiver originally began as an outgrowth from Indiana's original Healthy Indiana Plan (HIP) demonstration waiver. HIP 1.0 began in January 2008 with the purpose of supplementing state plan benefits for Medicaid eligible children and otherwise eligible adults who were not aged, blind, or disabled.

Although it was set to expire at the end of 2013, HIP 1.0 was extended for an additional year through December 31, 2014. In May of the extension year, CMS approved an amendment allowing the State to include individuals diagnosed with ESRD who were at risk of losing supplemental coverage due to the Indiana's transition from 204(b) status to 1634.

This population included individuals diagnosed with ESRD who were enrolled under the State's spend-down program as of May 31, 2014 and were 1) eligible for Medicare; 2) were not institutionalized; and 3) had income over 150% of the federal poverty level (FPL). The amendment allowed the State to continue providing supplemental coverage and needed access to a highly vulnerable population with virtually no other options for supplemental coverage.

In January 2015, CMS approved the Healthy Indiana Plan 2.0 (HIP 2.0). All HIP 1.0 populations were subsequently transitioned to HIP 2.0 except for the ESRD population. In order to develop a more permanent solution, HIP 1.0 continued to operate under temporary extension until July 28, 2016 when CMS renewed the waiver for a five-year extension and renamed it: *End Stage Renal Disease §1115 Demonstration Waiver* (Project Number 11-W-00237/5). The current ESRD demonstration is effective through December 31, 2020.

The State has continued to operate the ESRD demonstration with the goal of ensuring access to supplemental coverage for a small but highly vulnerable ESRD population. This population continues to face many of the same obstacles it did when the waiver began in 2014. ESRD individuals are still generally foreclosed from enrolling in Medicare Advantage (MA) plans as well as purchasing supplemental coverage through the federal marketplace. Furthermore, Indiana does not require guaranteed issue of Medigap policies for individuals under 65, which effectively limits access to younger individuals with ESRD. The §1115 ESRD demonstration waiver enables this population to maintain necessary supplemental coverage for treatment that allows them to remain on kidney transplant lists.

Overview:

This demonstration will continue to provide coverage for individuals with ESRD that are not otherwise eligible to receive Medicaid services. The demonstration covers approximately 350 individuals with ESRD, who would otherwise be unduly burdened in procuring supplemental kidney transplant services and would be at an increased risk of removal from kidney transplant lists. With the ESRD demonstration extension, Indiana expects to improve on previous waiver objectives, drive increased access to supplemental coverage for ESRD waiver enrollees, and foster improved ESRD program outcomes.

The ESRD §1115 demonstration waiver includes two distinct populations that are eligible for supplemental wraparound services provided through the Medicaid state plan. Table 1 provides a general overview of both populations and the respective criteria for demonstration eligibility:

Table 1: ESRD Demonstration Waiver Populations

Description	Eligibility Criteria	Demonstration Population
Former spend down enrollees effective May 31, 2014	Enrolled in Medicaid spend down effective May 31, 2014, have Medicare, have resources less than \$1,500 for an individual and \$2,250 for a couple, have income over 150% of FPL, have a diagnosis of ESRD, are not institutionalized, and meet all other criteria, but not otherwise Medicaid eligible.	Population 1
New Enrollees	Income between 150% and 300% of FPL, have Medicare, have a diagnosis of ESRD, have resources less than \$1,500 for an individual and \$2,250 for a couple, are not institutionalized, and meet all other Medicaid non-financial eligibility criteria but are not otherwise Medicaid or Demonstration Population 1.	Population 2

The state anticipates that, similar to the previous waiver timeline, a draft of the evaluation report will be submitted to CMS by May 2, 2021 which is roughly 120 days from the effective date of the renewal

(1/1/2021). The State expects to engage in discussions with CMS as well as receive feedback on the draft evaluation design. After receiving CMS feedback on its draft evaluation design, the State will work to submit its final evaluation design to CMS no later than 60 days after. Depending on the timing of comments and feedback, the State anticipates final evaluation design submission in July or August of 2021.

Demonstration Hypotheses:

The ESRD §1115 waiver will investigate the following hypotheses:

- 1) ESRD §1115 waiver enrollees will maintain access to kidney transplant waiting lists.
- 2) ESRD §1115 waiver enrollees will have access to kidney transplants and the supplemental coverage needed to ultimately end their ESRD diagnosis and increase access to a broader market of health coverage.
- 3) The ESRD §1115 waiver demonstration will enroll newly-eligible individuals.
- 4) The ESRD §1115 waiver will promote awareness and enrollment of ESRD waiver recipients in Medicare Advantage (MA) plans.

To test these hypotheses, the ESRD §1115 waiver will utilize the following evaluation measures:

- Track waiver enrollment and enrollment trends over the course of the demonstration
- Track waiver enrollees who are on the transplant list as well as those who are not.
- Track how many individuals on the waiver receive a kidney transplant.
- Track how many enrollees become ineligible for the waiver due to no longer having an ESRD diagnosis.
- Track how many newly-eligible enrollees gain coverage under the waiver.
- Track total and average waiver spend-down totals for ESRD waiver recipients and the frequency with which ESRD waiver liability is met annually
- Track total expenditures associated with ESRD waiver enrollees.
- Track specific Medicare enrollment type (Fee-for-service, MA, Medigap, etc.) for ESRD waiver enrollees.

Plan for Measurement and Analysis:

This evaluation will build on current and historical data and information regarding program enrollment, service utilization, and program costs. Several methods and sources for collecting information will be utilized and potentially developed. Medicaid enrollment data, information from claims, other Medicaid and social services data, as well as any relevant and identifiable data obtained through inter-agency information-sharing agreements will also provide a basis for analysis. The sample for the ESRD §1115 waiver will be all enrollees whose eligibility for the waiver has been established.

The effects of the demonstration are isolated from other initiatives occurring in the state, as there are no other initiatives in Indiana regarding ESRD. Additionally, enrollees in the waiver are not eligible to receive other Medicaid services.

Questions to be addressed in the evaluation include:

- 1) How many people are enrolled in the ESRD waiver?
- 2) How many enrollees are on the kidney transplant list during enrollment?
- 3) How many enrollees received a kidney transplant during enrollment?
- 4) How many enrollees no longer have a diagnosis of ESRD?
- 5) How many new enrollees become eligible for the program?

- 6) What is the average amount of ESRD waiver spend-down?
- 7) What are the ESRD enrollee expenditures?
- 8) What type of Medicare are ESRD members enrolled?

In order to ensure access to comprehensive coverage for low-income individuals with ESRD with primary coverage through Medicare, the state will monitor utilization of HEDIS-like measures assessing Flu vaccinations for adults (FVA and FVO), Adults’ Access to Preventive/Ambulatory Health Services (AAP), and Ambulatory Care (AMB). Measures, data sources, and populations for the demonstration are listed in Table 2:

Table 2: Measures, Data Sources and populations for Descriptive Analyses

Measures	Data Sources	Population
Number of unique enrollees diagnosed with ESRD	<ul style="list-style-type: none"> • Data Warehouse • Claims • Social Services Warehouse 	Population 1 and Population 2
Number of unique enrollees who are on the transplant list	<ul style="list-style-type: none"> • Data Warehouse • Claims • Social Services Warehouse 	Population 1 and Population 2
Number of unique enrollees on the waiver who received a kidney transplant	<ul style="list-style-type: none"> • Data Warehouse • Claims • Social Services Warehouse 	Population 1 and Population 2
Number of unique enrollees end coverage on the waiver due to no longer having the diagnosis of ESRD	<ul style="list-style-type: none"> • Data Warehouse • Claims • Social Services Warehouse 	Population 1 and Population 2
Number of enrollees who expired due to ESRD during enrollment	<ul style="list-style-type: none"> • Data Warehouse • Claims • MOUs/Data-sharing with the IN State Department of Health 	Population 1 and Population 2
Number of claims and associated expenditures	<ul style="list-style-type: none"> • Data Warehouse • Claims 	Population 1 and Population 2

NOTE: data for each of the populations will be calculated for each population separately, with totals for both populations. In addition, the state will determine if the measures in this table can better be represented as proportions or percentages in order to give context to the data.