

Draft Evaluation Design
End Stage Renal Disease (ESRD) Section 1115(a)
Demonstration Waiver

Indiana Family and Social Services Administration
Office of Medicaid Policy and Planning
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DRAFT EVALUATION DESIGN
END STAGE RENAL DISEASE (ESRD) Section 1115(a) DEMONSTRATION WAIVER

Introduction:

The End Stage Renal Disease (ESRD) 1115 demonstration waiver will allow Indiana to provide Medicare-enrolled individuals with ESRD, who are otherwise ineligible for Medicaid, with supplemental wrap-around coverage including supplemental coverage for kidney transplant services. ESRD enrollees are Medicare beneficiaries in need of supplemental health care coverage. By providing coverage through the Healthy Indiana Plan (HIP), beneficiaries were able to access kidney transplant and related services that they might not be able to afford without the additional supplemental benefits.

The goals of this approved demonstration are to:

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

The State of Indiana respectfully submits End State Renal Disease (ESRD) Section 1115(a) Demonstration Waiver Draft Evaluation Design.

Background:

Indiana's HIP 1.0 demonstration began in January 2008 to supplement state plan benefits for Medicaid eligible children and otherwise eligible adults who are not aged, blind or disabled. HIP 1.0 was scheduled to expire at the end of 2013, but was extended for an additional year through December 31, 2014. In May 2014, CMS approved an amendment to include former spend down enrollees diagnosed with End Stage Renal Disease (ESRD) as a HIP 1.0 demonstration population.

In January 2015, CMS approved the Healthy Indiana Plan 2.0 (HIP 2.0) demonstration whereby former HIP 1.0 enrollees transitioned into the HIP 2.0 demonstration; the ESRD enrollees were the only population remaining in the HIP 1.0 demonstration. The HIP 1.0 demonstration with only the ESRD enrollees operated on a temporary extension until its approval on July 28, 2016 and renamed the End Stage Renal Disease (ESRD) Demonstration

Overview:

This demonstration will continue to provide coverage for individuals with ESRD that are not currently eligible under the Medicaid state plan. The demonstration covers approximately 350 individuals with ESRD, who would otherwise be unable to access kidney transplant services. With this demonstration extension, Indiana expects to achieve program objectives.

This demonstration includes two populations who are made eligible under the Demonstration Waiver. Table 1 contains an overview of eligibility under the Demonstration Waiver.

Table 1—ESRD Demonstration Waiver Populations

Description	FPL Level and/or Other Qualifying 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

Special Terms and Conditions:

The evaluation requirements for the Demonstration Waiver are enumerated in Section III of the Special Terms and Conditions, and include:

39. Submission of Draft Evaluation Design - The state must submit to CMS for approval an updated draft evaluation for an overall evaluation of the demonstration by no later than 120 days after the effective date of the demonstration. At a minimum, the draft design must include a discussion of the goals and objectives set forth in Section II of these STCs, as well as the specific hypotheses that are being tested. The draft design must discuss the outcome measures that will be used in evaluating the impact of the demonstration during the periods of approval. It shall discuss the data sources and sampling methodology for assessing these outcomes. The draft evaluation design must include a detailed analysis plan that describes how the effects of the demonstration must be isolated from other initiatives occurring in the state. The draft design must identify whether the state will conduct the evaluation, or select an outside contractor for the evaluation. The state will conduct the evaluation in-house but with assistance provided by the Medicaid Medical Advisory Cabinet (MMAC) and/or the External Quality Review (EQR) vendor.

The state anticipates that the draft of the final report will be submitted by April 30, 2021, and the final report will be submitted in July or August 2021.

Demonstration Hypotheses:

The ESRD 1115 waiver will investigate the following hypotheses:

- a. ESRD 1115 waiver enrollees will maintain access to kidney transplant waiting lists.
- b. ESRD 1115 waiver enrollees will access kidney transplants, ending their diagnosis of ESRD and increasing their access to alternative forms of health insurance coverage.

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

- Track waiver enrollment
- Track waiver enrollees who are on the transplant list
- Track how many on the waiver receive a kidney transplant
- Track how many end coverage on the waiver due to no longer having ESRD diagnosis

Plan for Measurement and Analysis:

The evaluation will build on information about program enrollment, utilization, and costs. Several methods for collecting information will be utilized, including Medicaid enrollment, claims records and Medicaid data, and Indiana’s Social Services Warehouse. The sample for the ESRD 1115 waiver will be all enrollees deemed eligible for the waiver.

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 that will be addressed are:

1. How many enrollees are on the kidney transplant list during enrollment?
2. How many enrollees received a kidney transplant during enrollment?
3. How many enrollees no longer have a diagnosis of ESRD?
4. How many enrollees expired due to ESRD during enrollment? In order to ensure reliability, the state will verify the cause of death through claims, death certificates, and/or eligibility files.

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).

Table 2 contains the measures, data sources, and populations for the Demonstration.

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

Measures	Data Sources	Population
Number of unique enrollees diagnosed with ESRD	Data Warehouse Claims Social Services Warehouse	Population 1 and Population 2
Number of unique enrollees who are on the transplant list	Data Warehouse Claims Social Services Warehouse	Population 1 and Population 2
Number of unique enrollees on the waiver who	Data Warehouse	Population 1 and

received a kidney transplant	Claims Social Services Warehouse	Population 2
Number of unique enrollees end coverage on the waiver due to no longer having the diagnosis of ESRD	Data Warehouse Claims Social Services Warehouse	Population 1 and Population 2
Number of enrollees who expired due to ESRD during enrollment	Data Warehouse Claims MOU with the Indiana State Department of Health	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.

If there are any questions or comments regarding these changes please do not hesitate to contact the State contacts listed below.

State Contacts

Primary Contact	Secondary Contact
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