



**INDIANA END STAGE RENAL DISEASE
SECTION 1115 DEMONSTRATION WAIVER**

Sunset and Request for Temporary Extension

Project Number 11-W-00237/5

DRAFT FOR PUBLIC COMMENT

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Executive Summary

Approved on an emergency basis by the Centers for Medicare & Medicaid Services (CMS) on May 30th, 2014,¹ Indiana's section 1115 End Stage Renal Disease (ESRD) demonstration, authorized limited coverage to Medicare-enrolled individuals with ESRD who, at the time, were otherwise ineligible for Medicaid or Medicare supplemental wrap-around coverage, including supplemental coverage for kidney transplant services, and did not have another source of supplemental health coverage. ESRD demonstration enrollees are required to meet a monthly ESRD waiver liability that is calculated based on the phased out spend down methodology prior to being given access to the full range of Medicaid state plan benefits, including dialysis services needed to maintain their condition. The ESRD waiver coverage is not considered minimal essential coverage, but this demonstration allowed individuals with ESRD to remain on transplant lists and receive Medicaid coverage before, during, and after transplant provided they met their monthly ESRD liability amount. At the time of the initiation of the ESRD demonstration, Medicare Advantage excluded individuals with ESRD from enrollment.

Over the life of the demonstration, 760 individuals received coverage, with an approximate average of 400 enrollees receiving ESRD coverage each year². As of June 2023, a total of 218 individuals were enrolled. The latest interim evaluation conducted through March 2020, indicated that the ESRD program continued to meet the overall Medicaid program objective of the demonstration which is to provide supplemental health coverage of individuals with a diagnosis of ESRD who meet the income and asset limits of the demonstration. A trend of increasing kidney transplants corresponded with a trend of decreasing enrollment over the course of the demonstration.

In 2021, Medicare Advantage stopped exempting individuals with ESRD from enrollment in these plans, and the Indiana Office of Medicaid Policy and Planning, Family and Social Services Administration (FSSA) recognized that Medicare Advantage is a superior coverage option for individuals with ESRD currently enrolled in the ESRD demonstration. Medicare Advantage provides coverage that will cap individual out of pocket responsibilities and will allow individuals with ESRD to remain on transplant lists and receive transplants without requiring a monthly ESRD liability to be met before offering coverage. As a result, individuals enrolled in Medicare Advantage may receive kidney transplants and are no longer at risk of being removed from transplant lists in the absence of the ESRD 1115 demonstration. In addition, new Medicare Part B Immunosuppressive Drug (Part B-ID), which became available January 1, 2023, includes the provision for continued coverage of transplant drugs. With the new insurance options made available to ESRD patients with the passage of the 21st Century Cures Act, FSSA is proposing to sunset the ESRD section 1115 demonstration effective December 31, 2024, after allowing two Medicare open enrollment periods to assist individuals with enrollment in comprehensive coverage through Medicare Advantage.

Background Program Information

In 2014, a coverage gap was created for spend down enrollees with ESRD when Indiana transitioned from 209(b) to 1634 status and removed the spend down program. At that time, Individuals under the

¹ The emergency ESRD approval was added to the existing original Healthy Indiana Plan Section 1115 waiver, originally approved in December 2007.

² This data will be updated before the final plan is submitted to CMS.

age of 65 with ESRD were not allowed to enroll in Medicare Advantage, did not have Special Needs Plans available to them, and the state did not have guaranteed issue rights for Medicare Supplement policies. Without a program to cover them, individuals with ESRD under age 65 could not get supplemental coverage for 20 percent coinsurance on Medicare Part B which would be applicable to transplant surgeon fees. These individuals risked not being eligible for a transplant without supplemental coverage. In May 2014, the ESRD population was added to the existing Healthy Indiana Plan waiver and has persisted on that waiver since, even as HIP transitioned to a new 1115 in January of 2015.

The original HIP demonstration, now titled HIP 1.0, was ultimately renewed by CMS in July 2016 under the new and current name, “End Stage Renal Disease (ESRD) Section 1115 Demonstration.” The program extended the spend down like coverage for this population to ensure the individuals could remain on transplant lists and receive kidney transplants.

Following a request to amend the HIP demonstration, on May 29, 2020 CMS added the “Workforce Bridge Account Program” to the ESRD demonstration instead of including it in the HIP waiver. The Workforce Bridge Account Program will support the successful transition from HIP to commercial insurance for individuals who lose access to Medicaid coverage because of increased income in order to reduce healthcare coverage gaps and improve overall access to care. Under this program, certain HIP beneficiaries would be informed that, if they lose their HIP eligibility solely due to an increase in income, they could be eligible for up to \$1,000 for the purpose of temporarily paying for costs that include premiums and copayments for health insurance coverage, or the direct costs of health care services that would be covered by HIP. Reimbursement for health insurance premiums will be paid to the individual or to the plan at the request of the individual enrolled in a Marketplace health plan. Indiana has not yet implemented this component of the demonstration in compliance with the Families First Coronavirus Response Act (FFCRA), enacted at the beginning of the coronavirus (i.e., COVID-19) pandemic that required states to provide continuous enrollment to Medicaid enrollees until the end of the month in which the public health emergency (PHE) ends in order to receive enhanced federal funding to address challenges associated with the COVID-19 pandemic.

The Indiana ESRD section 1115 demonstration has otherwise generally operated as renewed annually by CMS, with only slight variations implemented in terms of eligible populations. The current ESRD section 1115 populations and benefits are listed in the below table.

Population	Eligibility Criteria	Benefits
Demonstration Population 1 – Former Spend Down Enrollees	<ul style="list-style-type: none"> • Enrolled in Medicaid spend down effective May 31, 2014 • Have income over 150% of the Federal Poverty Level (FPL), with no upper limit • Current diagnosis of End-Stage Renal Disease • Enrolled in Medicare part A and B • Have resources less than \$2,250 for an individual, less than \$3,000 for a couple • Not institutionalized • Meet all other non-financial Medicaid eligibility criteria, but are not otherwise eligible for Medicaid 	<p>State plan benefits after Medicaid ESRD waiver liability is met and non-emergency medical transportation</p> <p>Excluded services:</p> <ul style="list-style-type: none"> • Swing bed in a skilled nursing facility • Long-term care services (nursing facility, home and community-based waiver, and ICF/IID services)

Population	Eligibility Criteria	Benefits
Demonstration Population 2 – New Enrollees	<ul style="list-style-type: none"> • Have income between 150% and 300% FPL • Current diagnosis of End-Stage Renal Disease • Enrolled in Medicare part A and B • Have resources less than \$2,250 for an individual, less than \$3,000 for a couple • Not institutionalized • Meet all other non-financial Medicaid eligibility criteria, but are not otherwise eligible for Medicaid or Demonstration Population 1 	<p>State plan benefits after Medicaid ESRD waiver liability is met and non-emergency medical transportation</p> <p>Excluded services:</p> <ul style="list-style-type: none"> • Swing bed in a skilled nursing facility • Long-term care services (nursing facility, home and community-based waiver, and ICF/IID services)
Demonstration Population 3 – Workforce Bridge Account	<ul style="list-style-type: none"> • Individuals who are no longer eligible for HIP under section 1902(a)(10)(A)(i)(VIII) due to a verified increase in income 	Up to \$1,000 for the purpose of paying health insurance premiums, cost-sharing, and/or the direct costs of prescription drugs and services otherwise coverable under section 1905(a) of the Social Security Act

The state has continued to operate the current ESRD demonstration in alignment with the original goal of ensuring access to supplemental coverage for a small but highly vulnerable population. Indiana has remained in compliance with all CMS Special Terms and Conditions (STCs) of approval over the course of the demonstration. Indiana is current on all quarterly and annual monitoring requirements, including budget neutrality; reporting no complaints, problems, or quality assurance issues identified with the program.

Overall, the ESRD section 1115 demonstration has allowed individuals with ESRD who did not have another source of supplemental coverage the ability to remain on transplant lists and receive comprehensive health coverage before, during, and after transplant. In _____, Congress enacted the 21st Century Cures Act to allow all Medicare-eligible individuals with ESRD to enroll in Medicare Advantage plans beginning January 1, 2021. Prior to the passage of this law, patients with kidney failure were one of the only groups unable to enroll in Medicare Advantage with a few exceptions, such as patients who had already enrolled before their diagnosis or those who have successfully received a transplant. The ESRD section 1115 demonstration was the only supplemental coverage option that would cap the 20 percent Part B that was available for individuals over the Medicaid income limit who had Medicare but were under age 65.

With the new Medicare Advantage enrollment options created by the Cures Act, ESRD patients can enroll in Medicare Advantage which, unlike traditional Medicare Part A and Part B, acts as an “all in one” plan, that includes prescription (Part D) coverage and in some cases additional benefits such as vision, hearing, and dental (which traditional Medicare does not provide). Medicare Advantage provides ESRD patients, such as the individuals currently covered under the demonstration, advantages such as expanded benefits and other care services to improve patient quality outcomes, low premiums, and capped out-of-pocket costs. In light of the availability of comprehensive Medicare Advantage coverage to the individuals served under the ESRD section 1115 demonstration, Indiana is phasing-out the demonstration, after a requested 18-month transition period, with a proposed demonstration end date of December 31, 2024.

In accordance with CMS requirements for the ESRD section 1115 demonstration, Indiana is conducting tribal consultation and providing a 30-day public notice and comment period on this draft sunset plan. This plan also includes the transition of the Workforce Bridge Account Program from the ESRD demonstration to the HIP demonstration. In accordance with CMS STC 9, this draft sunset will be provided to CMS no less than 6 months before the planned effective date of the end of the demonstration. After completion of the 30-day public comment period described below, Indiana will finalize the draft sunset inclusive of public feedback and associated revisions for CMS approval to implement the plan. Indiana must obtain CMS' approval of the sunset plan prior to the implementation of the sunset activities described therein. Indiana will start implementing the sunset plan no sooner than 14 days after CMS approval.

Public Comment Information

The Indiana Office of Medicaid Policy and Planning initiated tribal consultation July 20, 2023 to September 18, 2023. The 30-day comment period for the tribe will run from August 19, 2023 to September 18, 2023.

The Indiana Office of Medicaid Policy and Planning, Family and Social Services Administration (FSSA) is seeking public comment on its draft sunset plan for the approved End Stage Renal Disease (ESRD) Section 1115 Demonstration and the transition of HIP Workforce Bridge from the ESRD demonstration to the Healthy Indiana Plan demonstration (Project Number 11-W-00237/5) to be submitted to CMS for approval, effective December 31, 2024.

The 30-day public comment period is available from August 16, 2023 through September 15, 2023.

Written comments may be directed to, FSSA, Office of Medicaid Policy and Planning, Attention: Madison May-Gruthusen, 402 West Washington Street, Room W374, MS02 Indianapolis, IN 46204 or by email to spacomment@fssa.in.gov. Correspondence should be identified in the following manner: COMMENT RE: ESRD SUNSET. Written comments will be made available for public inspection at the address herein of the OMPP.

The comments will be summarized and addressed in the final version of the sunset to be submitted to CMS.

Sunset Plan – Timeline and Activities

Please note that the below outline reflects the key significant activities reasonably expected to implement and complete an orderly sunset of the ESRD section 1115 demonstration over an 18-month period. The state may undertake additional activities as needed to support the sunset.

Date	Sunset Activity
July 20, 2023	FSSA provides tribal notice on the termination and upcoming draft plan to orderly sunset federal section 1115 authority for the ESRD section 1115 demonstration, effective December 31, 2024, to be posted on the FSSA website for 30-day public comment period.

Date	Sunset Activity
July 20, 2023	FSSA sends CMS draft sunset plan for informal review and comment to ensure alignment with federal requirements before opening 30-day public comment period.
August 16, 2023	FSSA publishes notice in state register.
August 16 – September 15, 2023	Draft sunset plan to end the ESRD section 1115 demonstration effective December 31, 2024, posted on FSSA website for 30-day public comment period.
September 16 - 26, 2023	At the end of the 30-day public comment period, review and summarize public comments to incorporate feedback into final draft sunset plan for submission to CMS for approval to implement.
By no later than September 29, 2023	Send final draft sunset plan for submission to CMS for approval.
October 1, 2023	FSSA sends written reminder to ESRD demonstration enrollees and their authorized representatives about the upcoming 2023 “Open Enrollment Period” for first time enrollment in Medicare Advantage (i.e., October 15 through December 7 of each year). Enrollment during the Open Enrollment Period goes into effect on January 1 of the following year.
Estimated by no later than October 30, 2023	FSSA receives CMS approval of sunset plan to begin implementation within 14 days of approval (<i>estimating a maximum 45-day approval period though there is no set timeframe for CMS to approve</i>).
November 1, 2023	FSSA sends written notice to providers about the upcoming planned sunset the ESRD section 1115 demonstration and actions required to prepare for the end of the demonstration program effective December 31, 2024.
November 15, 2023	FSSA sends written notices to ESRD demonstration enrollees about the upcoming planned sunset the ESRD section 1115 demonstration, what their beneficiary rights are in accordance with federal Medicaid requirements, and likely available options to access other healthcare coverage (including information on the ex parte redeterminations and open enrollment periods for Medicare Advantage) prior to the end of the demonstration.
December 2023	Begin necessary programming/coding changes, including closure notices to affected beneficiaries with appeal rights, in the state Transformed Medicaid Statistical Information System (T-MMIS), Medicaid eligibility system, and the Indiana Health Coverage Programs (IHCP) provider reference modules for billing and reimbursement.
January 2024	FSSA provides notice on the date that new enrollment into the ESRD section 1115 demonstration will cease to permit orderly close-out of demonstration enrollees by December 31, 2024.
March-April 2024	FSSA sends written follow-up/reminder notice to providers about the upcoming sunset the ESRD section 1115 demonstration and any actions required to prepare for the end of the demonstration program effective December 31, 2024.
July 1, 2024	FSSA ends enrollment of new individuals in the ESRD section 1115 demonstration.

Date	Sunset Activity
September 2024	FSSA completes all necessary programming/coding changes to state Medicaid systems (i.e., T-MMIS), Medicaid eligibility system, IHCP provider modules).
By no later than October 1, 2024	FSSA sends final written reminder notice to beneficiaries about the sunset of the ESRD section 1115 demonstration and the upcoming 2024 “Annual Fall Enrollment Period” for first time enrollment in Medicare Advantage (i.e., October 15 through December 7 of each year). Enrollment during the Fall Enrollment Period goes into effect on January 1 of the following year. <i>This is the last Medicare Advantage Enrollment Period before the ESRD section 1115 demonstration ends on December 31, 2024.</i>
October 2024	FSSA sends final written reminder notice to providers about the upcoming sunset of the ESRD section 1115 demonstration and any actions required to prepare for the end of the demonstration program effective December 31, 2024.
December 2024	Final closure notices sent to affected beneficiaries at least 13 days prior to effective date of closure.
December 31, 2024	Demonstration ends on December 31, 2024
April 30, 2025	Final Close-out Report to CMS due 120 days after the expiration of the demonstration (i.e., by no later than April 30, 2025).
June 30, 2026	Final Summative Evaluation Report due to CMS within 18 months after the end of the demonstration period (i.e., by no later than June 30, 2026).

Communication with Members and Stakeholders

In 2020, in partnership with the Indiana State Health Insurance Information Program (SHIP), FSSA sent a letter to all ESRD demonstration waiver participants as well as non-waiver participants who were on Medicaid diagnosed with ESRD. Letters were mailed to 224 waiver and 4,608 non-waiver enrollees. The letters contained information on Medicare Advantage and open enrollment, which took place from October 15, 2020 to December 7, 2020. As indicated in the timeline above, FSSA will send written reminders to ESRD demonstration enrollees about the upcoming 2023 “Annual Fall Enrollment Period” for first time enrollment in Medicare Advantage (i.e., October 15 through December 7 of each year). Enrollment during the Fall Enrollment Period goes into effect on January 1 of the following year.

On November 1, 2023, FSSA will send written notice to providers about the upcoming planned sunset of the ESRD section 1115 demonstration and actions required to prepare for the end of the demonstration program. Two weeks later, FSSA will send written notices to ESRD demonstration enrollees about the upcoming planned sunset, what their beneficiary rights are in accordance with federal Medicaid requirements, and likely available options to access other healthcare coverage prior to the end of the demonstration. Written follow-up/reminder notices to providers and final written reminder notices to members will be sent in March 2024 and October 2024 respectively.

Prior to member disenrollment from ESRD coverage, the final sunset, the eligibility system will explore eligibility for that member in any other Indiana Medicaid categories of assistance. The system reviews

potential eligibility based on established categorical requirements based on specific income and resource requirements which vary according to the category and family circumstances. The hierarchy used for reviewing eligibility uses failure logic, starting with the most comprehensive scope of coverage available to the member and moving down the hierarchy through lesser levels of coverage. If a member is deemed ineligible for any category, they will receive a notice of closure with their appeal rights listed.

Temporary Extension Request

As part of FSSA's plan to complete an orderly sunset of the ESRD section 1115 demonstration over an 18-month period, the state is requested that CMS approve a 12-month temporary extension of the demonstration. Approval was received June 23, 2023 and the demonstration is currently set to expire December 31, 2024.

As outlined in the above draft sunset plan, the 18-month period allows FSSA to: 1) permit ESRD demonstration enrollees to avail themselves of two open Medicare Advantage Fall Open Enrollment periods to effectuate Medicare Advantage coverage by no later than January 2024; 2) permit the state to work with other ESRD demonstration enrollees who may not enroll in Medicare Advantage to find access to other coverage options; 3) to transition the "Workforce Bridge Account" component of the ESRD section 1115 demonstration (without change) into the HIP section 1115 demonstration; 4) to develop and implement a communication strategy for collaborations with stakeholders on the orderly sunset the demonstration; and 5) complete programming/system changes to align with the termination of the ESRD demonstration.

FSSA appreciates CMS's granting of the 12-month temporary extension to extend the demonstration until December 31, 2024, subject to the same terms and conditions as currently approved. As previously instructed by CMS in the November 2022 temporary extension, the state intends to include this temporary extension and the prior temporary extension periods in the evaluation activities and summative evaluation as well as in the final close-out report to be completed for the full approval period after the expiration of the demonstration.