DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-25-26
Baltimore, Maryland 21244-1850

State Demonstrations Group

November 25, 2024

Cora Steinmetz
Director of Medicaid
Indiana Medicaid
State of Indiana, Family and Social Services Administration
402 West Washington Street, Room W461, MS 25
Indianapolis, IN 46204

Dear Director Steinmetz:

The Centers for Medicare & Medicaid Services (CMS) completed its review of the Interim Evaluation Report, which is required by the Special Terms and Conditions (STCs), specifically STC #48 "Final Evaluation Design and Implementation" of Indiana's section 1115 demonstration "End Stage Renal Disease (ESRD)" (Project Number #11-W-00237/5), effective through December 31, 2024. This Interim Evaluation Report covers the period from May of 2017 through March of 2020. CMS determined that the Evaluation Report, submitted on May 13, 2020 and revised on December 1, 2022, is in alignment with the CMS-approved Evaluation Design and the requirements set forth in the STCs, and therefore, approves the state's Interim Evaluation Report.

The findings from the evaluation are positive but limited, in part due to the small population of enrollees in the ESRD demonstration. Descriptive trends show that between 2014 and 2020, there were a total of 760 unique individuals enrolled in the program. Over this time period, the total number and percent of members with a kidney transplant claim increased, while the total number and percent of members with a dialysis claim decreased, in line with the demonstration's goal of increasing transplants and, as a result, decreasing the need for dialysis in the demonstration population and ultimately decreasing the number of members in the demonstration. Additionally, costs per member per month slightly increased over the duration of the demonstration. CMS looks forward to receiving the Final "Summative" Evaluation Report.[1]

In accordance with STC #48 "Final Evaluation Design and Implementation", the approved Interim Evaluation Report may now be posted to the state's Medicaid website within 30 days. CMS will also post the Interim Evaluation Report on Medicaid.gov.

[1] The demonstration's STCs approved on July 28, 2016 require the state to complete a Final Evaluation Report, which CMS has since referred to in more recent demonstration approvals as a Summative Evaluation Report. For alignment with Indiana's ESRD demonstration STCs, we refer to this report as the Final Evaluation Report.

We look forward to our continued partnership on the ESRD section 1115 demonstration. If you have any questions, please contact your CMS demonstration team.

Sincerely,

Danielle Daly -S Digitally signed by Danielle Daly -S
Date: 2024.11.25 12:23:31 -05'00'

Danielle Daly
Director
Division of Demonstration Monitoring and Evaluation

cc: Rhonda Gray, State Monitoring Lead, CMS Medicaid and CHIP Operations Group

INDIANA FAMILY AND SOCIAL SERVICES ADMINISTRATION

Interim Evaluation for Indiana End-Stage Renal Disease Section 1115 Waiver

May 13, 2020

Contents

Executive Summary

Indiana's §1115 End Stage Renal Disease (ESRD) demonstration waiver affords individuals with ESRD who do not have another source of supplemental coverage the ability to remain on transplants lists and provides comprehensive health care coverage for enrollees before, during and after transplant. Through the ESRD demonstration, enrollees retain access the full range of Medicaid State Plan benefits including dialysis services needed to maintain their condition. The program originally began as a development from Indiana's HIP 1.0 demonstration in 2008, and now serves two populations with slight variations in eligibility—those who became eligible for the program before May 31, 2014 and those who enrolled afterwards.

Between May 2014 and March 2020, the ESRD demonstration ensured coverage to 760 unique enrollees, covering on average approximately 400 unique enrollees per year. A trend of increasing kidney transplants corresponded with a trend of decreasing enrollment over the course of the demonstration, and this current evaluation indicates that the ESRD program continues to meet the goals and objectives as established at the onset of this demonstration.

General Background Information

The §1115 End Stage Renal Disease (ESRD) demonstration waiver originally began as development from Indiana's HIP 1.0 demonstration, which began January 2008 with the purpose of supplementing state plan benefits for Medicaid eligible children and otherwise eligible adults who are 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 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 approved a five-year extension and renamed the extension "End Stage Renal Disease (Project Number 11-W-00237/5)." Indiana's current §1115 ESRD demonstration waiver is effective through December 31, 2020.

The State has continued to operate its current ESRD demonstration with the goal of ensuring access to supplemental coverage for a small but highly vulnerable 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 plans through the federal marketplace. Furthermore, Indiana insurance code does not provide for guaranteed issue of Medigap policies for individuals under 65, which effectively limits access to younger individuals with ESRD. The §1115 ESRD demonstration waiver allows this population to maintain the supplemental coverage needed to remain in good standing on transplant lists. In doing so, this demonstration helps to

achieve the "Triple Aim" of improving individual and population health while promoting fiscal healthcare responsibility.

This evaluation will cover the renewal period July 28, 2016 through March 31 2020. Data from May 1, 2014 through July 31, 2016 are also included in this evaluation to bring context to the entirety of the program's history. This evaluation is for a renewal of the ESRD demonstration. There are two minor changes that Indiana is requesting in the renewal.

1. Increase asset limits from $1,500 to $2,250 for individuals, and increasing assets limits from $2,000 to $3,000 for couples.
2. State will notify and communicate to members of the new Medicare Advantage 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.

The population groups impacted by the demonstration are summarized as follows:

Group	Eligibility Criteria
Population 1 – Former Spend Down Enrollees	• **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
Population 2 – New Enrollees	• **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

Evaluation Questions and Hypotheses

The ESRD 1115 waiver goals 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. In order to address these goals, Indiana hypothesized that this waiver will maintain access to kidney transplant waiting lists, access to kidney transplants to end their diagnosis of ESRD, and increasing their access to alternative forms of health insurance coverage. In order to assess these hypotheses and goals, Indiana monitored the following metrics for both demonstration populations:

- ESRD waiver enrollment
- ESRD enrollees who are on the transplant list
- ESRD enrollee count of who received a kidney transplant
- ESRD disenrollment due to no longer having an ESRD diagnosis

Methodology

This evaluation looks at the §1115 waiver period starting July 28, 2016 through March 31, 2020. Data from May 1, 2014 through July 31, 2016 are included in this evaluation to provide context of the demonstration. The State is confident that the methodology employed to identify the ESRD waiver enrollees in this evaluation is the most accurate.

For background, in 2018 the State reviewed its internal controls related to budget neutrality and CMS 64 reporting. Through this review, it was identified that member enrollment and PMPMs were significantly higher than what the State expected, and what was estimated for the waiver period. Previously, enrollees were identified by having an ESRD diagnosis. Using only this distinction to identify the population, the numbers reported were significantly greater than those who were actually enrolled. The change in methodology reported in the Q2 2019 report was the discovery that all ESRD eligible members are "flagged" within the State's eligibility system at the local level of the field offices. For instance, the Q1 2018 Quarterly Monitoring report showed a total of 1,579 members enrolled (448 in Population 1 and 1,131 in Population 2). To compare, a total of 384 members were enrolled (42 in Population 1 and 342 in Population 2) when the methodology is employed in this report.

The new methodology described in this report identified eligible enrollees through three means to ensure an accurate ESRD waiver population is being reported. This methodology also enables the State to monitor this demonstration more accurately. The change in methodology utilized three methods for historical and current population identification.

1. During the State's inquiry to identify this population, it was discovered that all ESRD eligible members have an indicator, or "flag", that representatives at the local eligibility offices will tag members last authorized with reason code "425". Pulling the enrollee list with this indicator, the State's Data & Analytics team were able to identify the two population groups more accurately. Specifically, the Data & Analytics group used the following criteria to identify current enrollees:
    - Members currently OPEN in Medicare A, B, or D (MA A/B/D)
    - Institution Type 17 – END STAGE RENAL DISEASE
    - Last authorized with reason code 425
2. The State also utilized data transfer indicators from the T-MMIS file exchange to identify which members were tagged as an ESRD enrollee and had a spend down field associated with file. This method helped to identify historical and current ESRD enrollees.
3. Population 1 historical files that were provided by a State Contractor showed a larger Population 1 than previously identified in the two methods above. Since these historical data were considered to be accurate at the time of reporting when the demonstration was renewed, these members were manually captured and retained for Population 1.

It is not without notice that there are limitations associated with each of the methods described above. These limitations are outlined in the **Methodological Limitations** section below. The population under study is assumed to meet all the program requirements to be eligible for the ESRD provision as

described in the **General Background Information**.[1] Of those who meet the eligibility standards of the program requirement, there are two population groups.

> **Population 1 (Former Spend Down Enrollees):** The first group includes individuals enrolled in both Medicaid spend down and Medicare as of May 31, 2014, who had income over 150 percent FPL, and were losing access to spend down due to Indiana's transition to a 1634 state. This group met the spend down eligibility requirements in effect under the State's 209(b) rules as of May 31, 2014, which did not impose an upper income limit.
>
> **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, an upper income limit of 300 percent FPL was added for new enrollees. This income limit applies to all ESRD 1115 enrollees who were not on spend down as of May 31, 2014.

The metrics proposed to evaluate this demonstration are:

- **Number of unique waiver enrollees**
- Number of unique enrollees who are on the transplant list
- **Number of unique enrollees on the waiver who received a kidney transplant**
- Number of unique enrollees end coverage on the waiver due to no longer having the diagnosis of ESRD
- Number of enrollees who expired due to ESRD during enrollment
- **Number of claims and associated expenditures**

All of these metrics were originally developed and identified by the State. Some of these metrics, however, are not able to be included in this evaluation. This is due to several data limitations that will be outlined in detail below. Due to these significant data challenges, descriptive analyses of the ESRD population are provided. The measures included in this evaluation are bolded.

Measures	Data Sources	Population
Number of unique enrollees diagnosed with ESRD	**Data Warehouse** **Social Services Warehouse** **Claims**	**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 received a kidney transplant	**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	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	Population 1 and Population 2

[1] If an ESRD waiver enrollee becomes institutionalized in a Long Term Care facility (i.e. Nursing Home), they will be disenrolled from the ESRD waiver and not included in the respective quarter's count.

Measures	Data Sources	Population
	Department of Health	
Number of claims and associated expenditures	**Data Warehouse** **Claims**	**Population 1 and Population 2**

Methodological Limitations

The State has faced many data challenges in regards to identification of the ESRD enrollee population, especially identification of Population 1 (Former Spend Down enrollees), and challenges reporting some of the measures. Due to these significant data challenges, comprehensive and extensive statistical testing was not feasible.

Identification of ESRD enrollees and Population 1 enrollees

Several methods were employed to identify the ESRD waiver population due to many data limitations. Inconsistencies in FPL data transfer between the State's eligibility system and the Medicaid Management Information System (MMIS) resulted in null FPL values which appear as zero in the provided enrollment data and in some cases in the application of updated FPL numbers to prior months. For this reason, this evaluation used data transfer indicators from the T-MMIS file exchange to identify which members were tagged as an ESRD enrollee rather than identifying the members based on the eligibility requirements. In an effort to then further identify which population these enrollees belonged to, the State looked at the eligibility dates of each member. When the eligibility dates were queried based on the MMIS data, approximately 80% were then considered to be in Population 1. Based on working knowledge of this waiver, the State considered that number to be incorrect. Historical files with previous population identifiers were then combined to confidently identify the Population 1 enrollees. A total of 44 Population 1 enrollees were identified from these previous data pulls. For this evaluation, eligibility dates on the MMIS files were not considered for Population 1 identification, but rather historical data runs during the time when the state transitioned to a 1634 state.

Challenges with collection of evaluation measures

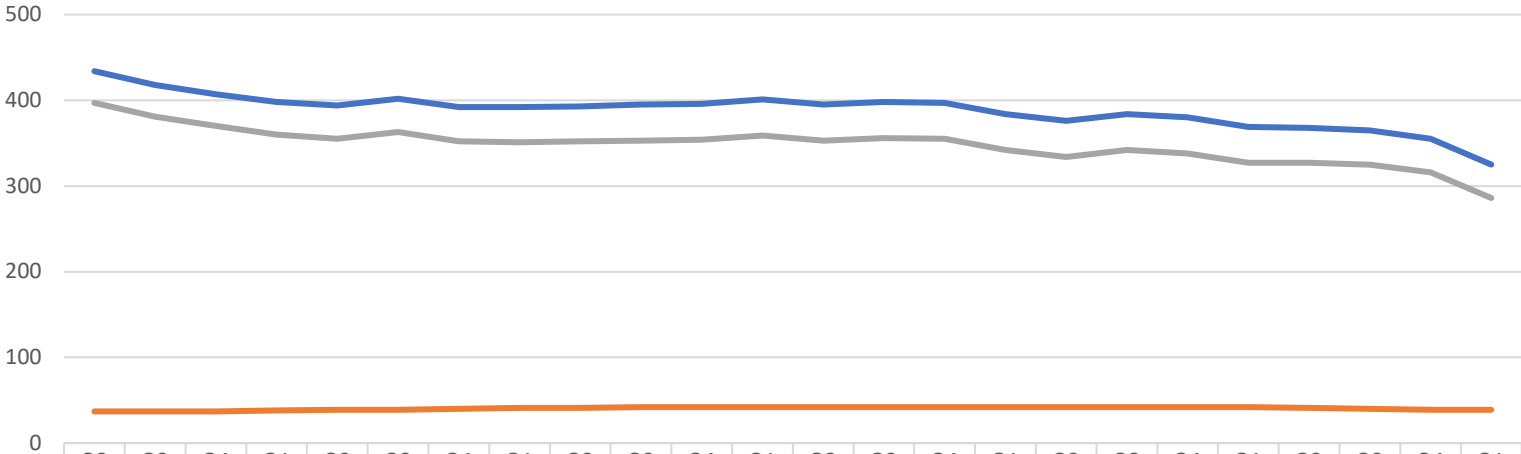
There are three measures that proved to be a challenge for the State collect, study, and include in this evaluation. The State could not ascertain the data from an external data source to understand the number of unique enrollees who were on the transplant list over the duration of the waiver period. It was also difficult for the State to identify if a member had expired due to ESRD during enrollment. The State is able to identify when and which enrollees have died, however it is more difficult to ascertain the cause of death for an individual was due to ESRD. The final measure that the State was not able to collect was the number of unique enrollees who end coverage on the waiver due to no longer having the diagnosis of ESRD. This waiver is in place to provide coverage for an ESRD enrollee before, during, and at least three years' post-transplant. If an individual receives a transplant at the beginning of the waiver period, it is plausible that they would continue coverage throughout the entirety of the demonstration. The State is committed to reassessing these measures in the next iteration of this waiver demonstration.

Results

Number of unique enrollees diagnosed with ESRD

From May 1, 2014 through March 31, 2020, there were a total of 760 unique ESRD waiver enrollees ever enrolled in this program. Total enrollment has decreased by 25% over the course of the waiver period. Population 1 enrollees make up approximately 9%-12%, and Population 2 enrollees make up 88%-91% of the total population. Quarterly enrollment counts can be found in Figure 1.

Figure 1: Number of unique enrollees diagnosed with ESRD by Population and quarter.



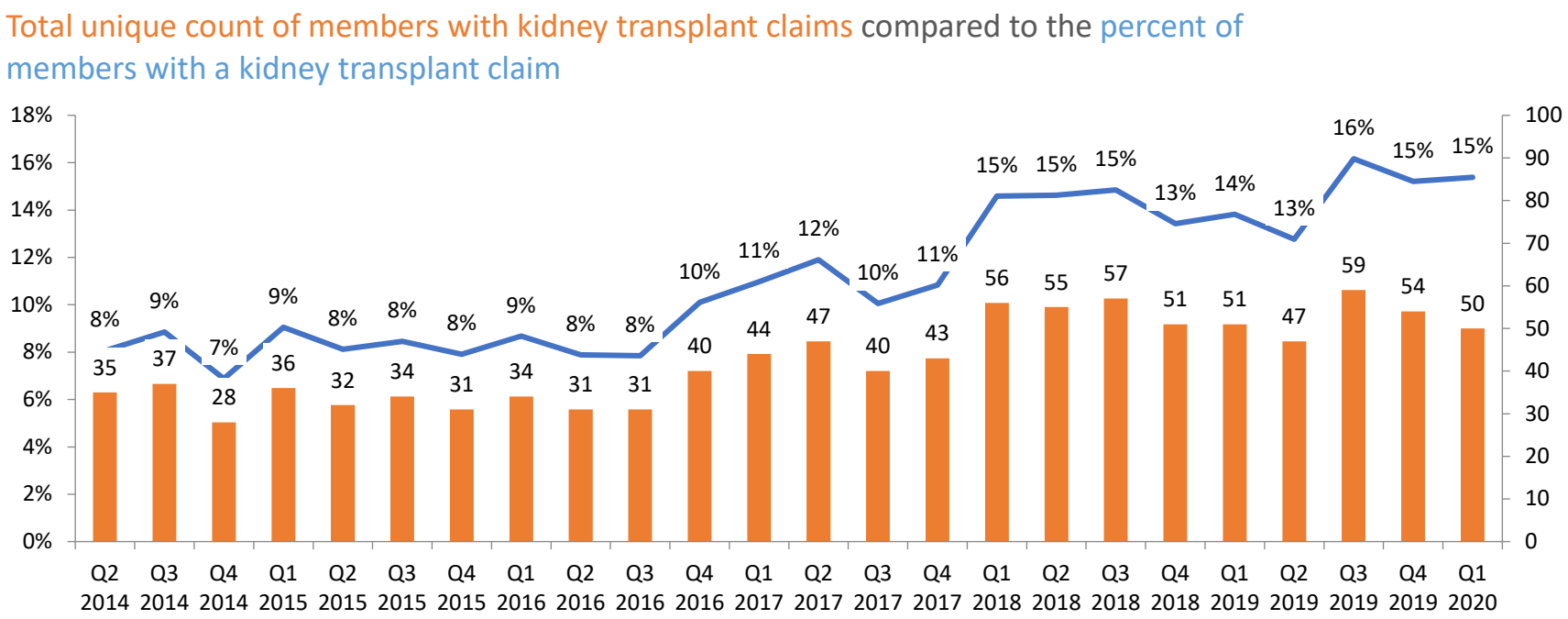
	Q2 2014	Q3 2014	Q4 2014	Q1 2015	Q2 2015	Q3 2015	Q4 2015	Q1 2016	Q2 2016	Q3 2016	Q4 2016	Q1 2017	Q2 2017	Q3 2017	Q4 2017	Q1 2018	Q2 2018	Q3 2018	Q4 2018	Q1 2019	Q2 2019	Q3 2019	Q4 2019	Q1 2020
Total	434	418	407	398	394	402	392	392	393	395	396	401	395	398	397	384	376	384	380	369	368	365	355	325
Population 1	37	37	37	38	39	39	40	41	41	42	42	42	42	42	42	42	42	42	42	42	41	40	39	39
Population 2	397	381	370	360	355	363	352	351	352	353	354	359	353	356	355	342	334	342	338	327	327	325	316	286

Figure 1 Q2 2014 includes May 1, 2014 through June 30, 2014

Number of unique enrollees on the waiver who received a kidney transplant

Over the course of the waiver period, there was a steady increase in total unique count of members with kidney transplant claims. The percent of members with a kidney transplant claim was derived by the unique number of enrollees who had a kidney transplant claim over total ESRD enrollment for that quarter. On average, unique kidney transplant claims increased by 58% when comparing 2015 and 2019. These two years were chosen because they represent the first and last complete years of the demonstration. The percent of members with a kidney transplant claim can be seen in Figure 2. Note that enrollees that receive a transplant will continue to have follow-up transplant claims, and a transplant claim in any quarter does not indicate that an actual transplant procedure was performed for that enrollee in that quarter.

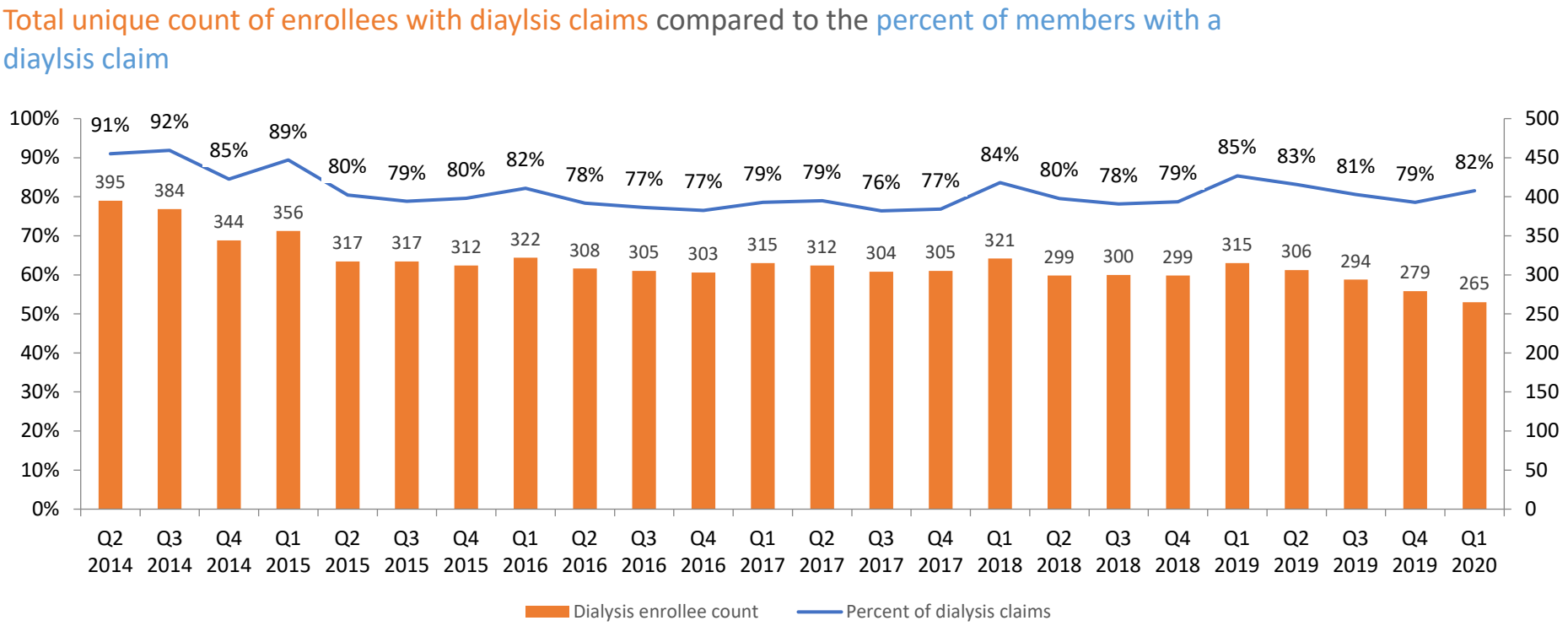
Figure 2: Total unique count of members with kidney transplant claims compared to the percent of members with a kidney transplant claim.



Number of unique enrollees on the waiver who had a dialysis claim

Over the course of the waiver period, there was a steady decrease in total unique count of members with dialysis claims. The percent of members with a dialysis claim was derived by the unique number of enrollees who had a dialysis claim over total ESRD enrollment for that quarter. This decline in dialysis over the course of the program is an expected result when looking at the increase in transplant claims. The decreasing trend in dialysis claims can be seen in Figure 3.

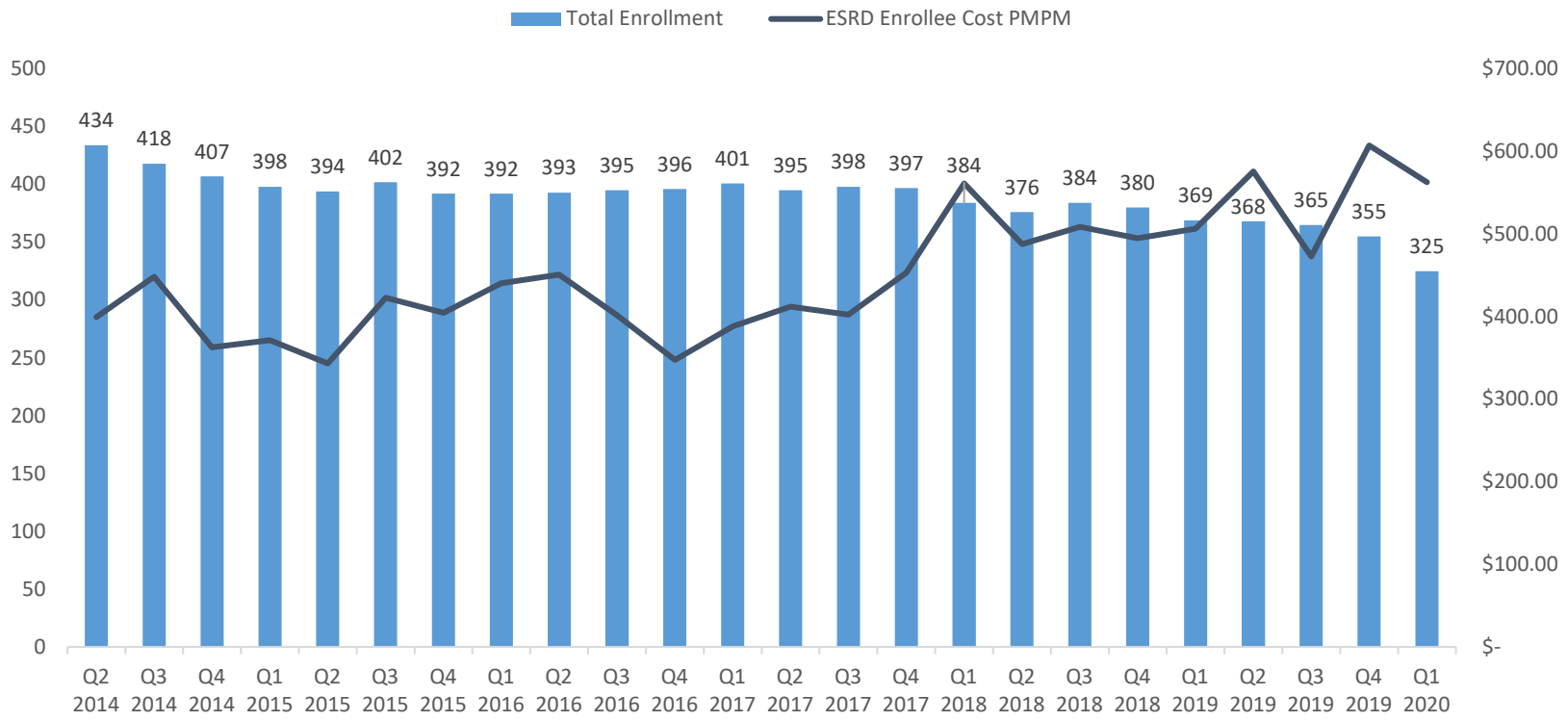
Figure 3: Total unique count of members with dialysis claims compared to the percent of members with a dialysis claim.



Number of unique enrollees on the waiver and cost per member per month.

Over the course of the waiver period, there was a steady decrease in total unique count of ESRD enrollees. This trend is expected due to the aforementioned trend in increasing kidney transplants illustrated within Figure 2. The cost of the ESRD enrollees per member per month (PMPM) is steadily increasing over the course of the waiver. These trends can be seen in Figure 4.

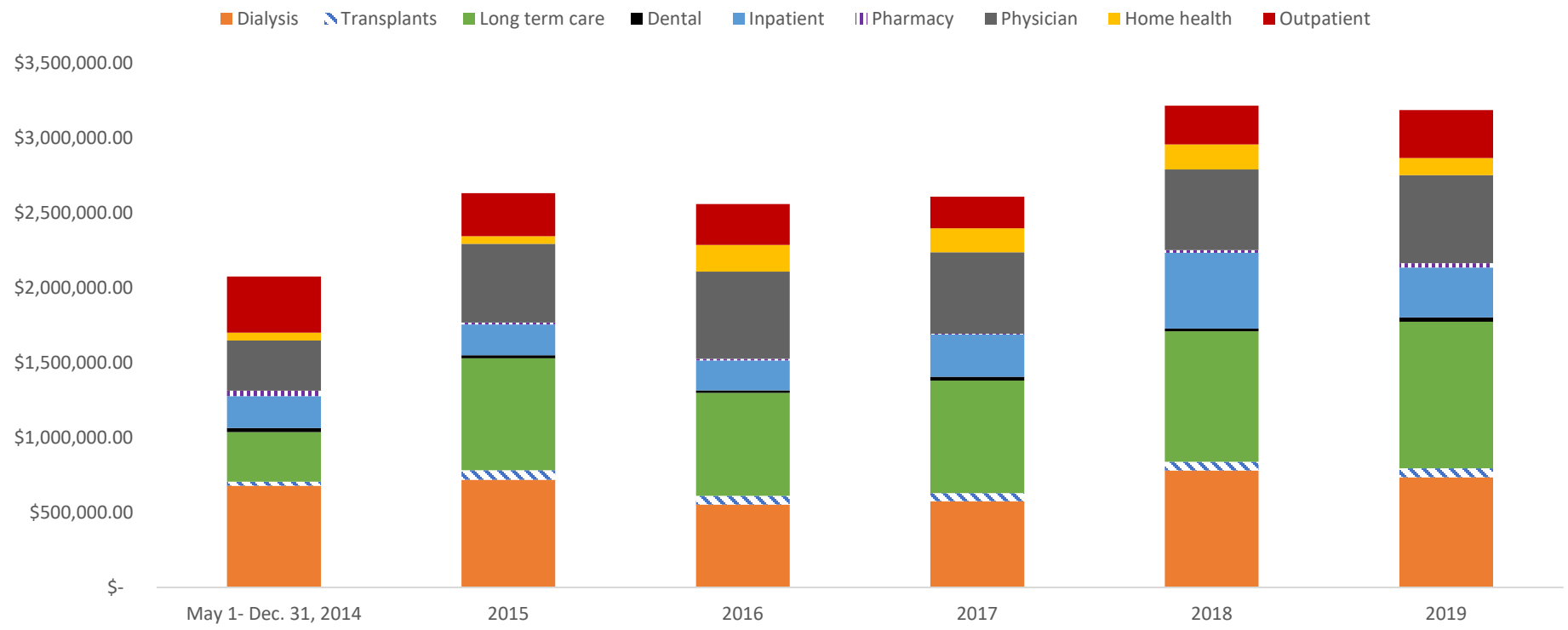
Figure 4: Total unique enrollment compared to enrollee cost PMPM



ESRD Health Care Utilization by Year

A yearly summary of health care utilization among ESRD enrollees, from 2014 through 2019, are presented in **Figure 5** below. The first quarter of 2020 was not included in the yearly analysis. Over the course of the demonstration, the total health care utilization expenditures increased for ESRD enrollees. Health care expenditures specifically for dialysis, long term care, inpatient, outpatient, and physician expenditures increased. **Figure 6** below gives context to the unique number of enrollees utilizing these services.

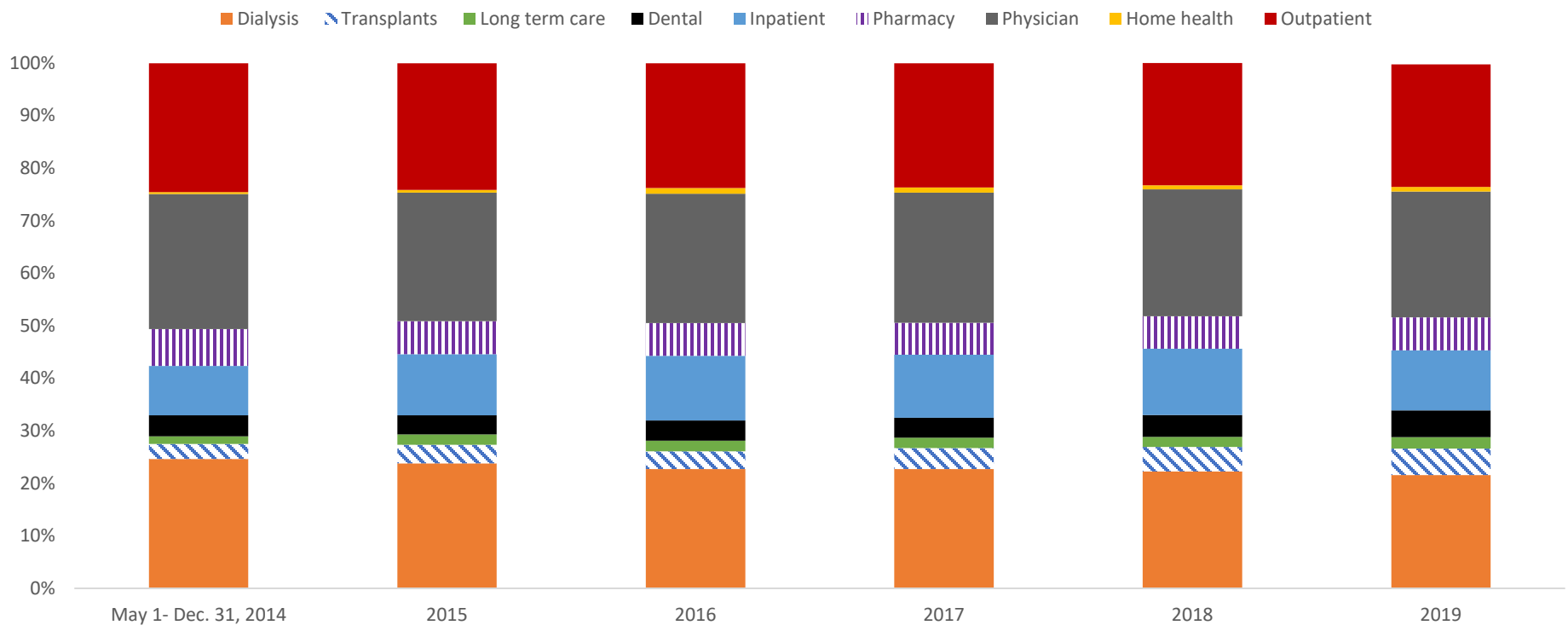
Figure 5: Health care utilization by year, 2014-2019



ESRD Health Care Utilization by Service Category

Figure 6 shows the proportion of unique enrollees who utilized a specific service category within the year. This figure gives context to the previous figure (**Figure 5**) which shows the proportion of expenditures per specific service category. For example, only 2% of ESRD enrollees have a long term care health expenditure across the waiver period but these claims represent a disproportionate amount of utilization seen in the previous figure (**Figure 5**).

Figure 6: ESRD Health Care Utilization by Service Category, 2014-2019.



Unique ESRD enrollee count by health care utilization category and by year

Figure 7 depicts the unique point in time health care expenditures by category and the unique count of enrollees accessing those expenditures per year.

	May 1- Dec. 31, 2014		2015		2016		2017		2018		2019	
Category	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*

Conclusions, Interpretations and Policy Implications

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—about ten new enrollees 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 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.

The State has met the goals and objectives of this waiver, but data challenges do persist. These challenges are a product of many factors but can be summarized as the constant uncertainty of the outlook and programing of this demonstration throughout the program's history. An uncertain outlook, combined with eligibility system changes, and a lack of standardization of reporting measures created obstacles. These challenges, however, do not outweigh the fact that this demonstration has provided access to comprehensive coverage and an enrollee's ability to stay on the transplant list and hopefully receive a transplant.

Lessons Learned and Recommendations

The evaluation of this demonstration has shown that enrollees are accessing transplant lists and are receiving comprehensive health care coverage. By completing the exercise of this evaluation, some of the data limitations have been addressed, such as accurate identification and verification of the ESRD enrollees. Similarly, the lack of standardization and competing methodologies were worked through so the State can move forward with additional completing analyses and answering questions that emerged through this exercise. For example, the State intends to examine whether enrollees will begin to access health care coverage through a Medicare Advantage plan, since this may be a more suitable option for them in the near future.

Although the need for supplemental coverage for the ESRD population is not a common occurrence across states, this demonstration provides strong evidence of the utility of a diagnosis-specific health care program. Of particular importance, the success of Indiana's §1115 ESRD demonstration waiver has direct policy implications for the current COVID-19 pandemic, as health officials evaluate options to best address the unique health care needs within individual states. Through Indiana's efforts, other states now have a blueprint on how to implement a diagnosis-specific health care intervention which state health officials can leverage in their efforts to address COVID-19.

Attachment(s)

1) Evaluation Design: Provide the CMS-approved Evaluation Design (available here: https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/in/esrd/in-esrd-final-eval-dsgn-03222017.pdf)