

# ETC Model: How One Small Dialysis Organization Is Navigating Uncharted Policy Waters



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**The ETC model proposes to increase access to home dialysis and transplant for patients with ESRD. Implementation of this model is happening while many dialysis organizations are still suffering the far-reaching effects of the coronavirus disease 2019 (COVID-19) pandemic. In addition, the model has the potential to negatively affect small and independent dialysis organizations disproportionately. It incentivizes home dialysis over transplant and promotes development of new home dialysis programs, rewards achievement over improvement, and places an excessive burden on small and independent dialysis organizations. Advantages of the program include the focus on self-care as an acceptable alternative to home dialysis for some patients and the potential for some organizations to make improvements in care with increased reimbursements. The authors hope that the Centers for Medicare and Medicaid Services will address many of these concerns in updated rulemaking and guidance.**

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**Key Words:** ETC model, SDO, IDO, Home dialysis, Kidney transplant

Start by doing what is necessary; then do what is possible, and suddenly you are doing the impossible.

— St. Francis of Assisi

ESRD beneficiaries account for approximately 1% of the Medicare population and 7% of total fee-for-service (FFS) Medicare expenditure.<sup>1</sup> In 2016, only 12% of Medicare beneficiaries were dialyzing at home in the United States. The US performance on home dialysis was low compared with other developed nations such as Hong Kong (74%), New Zealand (47%), Australia (28%), and Canada (25%). Similarly, with 39 transplants per 1000 dialysis patients, the United States lagged behind other industrialized nations.<sup>2</sup>

On September 29, 2020, the Centers for Medicare and Medicaid Services (CMS) published the Final Rule of End-Stage Renal Disease Treatment Choices (ETC) model. The Department of Health Human Services responded to the charge to take bold action to transform how kidney diseases are prevented, diagnosed, and treated within the next decade. Its stated rationale was to increase ESRD beneficiary treatment choices and home dialysis and kidney transplant rates by payment enhancements and penalties. However, these payment enhancements and penalties are weighted heavily in the favor of home dialysis. Participation is mandatory on the part of the enrolled dialysis providers and facilities, and the model will run from January 1, 2021, through June 30, 2027. Medicare beneficiaries may only “opt out” by transferring to a nonenrolled facility. We believe that the ETC model will fundamentally change the way business is conducted by SDOs/IDOs in the years to come and may seriously impact these organizations’ financial viability.

CMS randomly selected 96 out of 306 hospital referral regions (HRRs) to participate in the model. Of the 2463 dialysis facilities in the selected geographic areas, 97 facilities either did not have a home dialysis program or have a corporate relationship with a home dialysis program in the HRR as of 2020. The majority of these facilities appear

to belong to SDOs/IDOs. Availability and distribution of home programs are highly skewed. While the dialysis facilities in the large dialysis organizations (LDOs) almost always have a home dialysis program or a relationship with another entity in their organization within the same HRR, only 28% of SDOs/IDOs have similar relationships. Home dialysis is a valuable treatment option, but it comes with significant start-up and operational costs. We often find that patients come to dialysis with misconceptions about home dialysis that lead to a hesitation to consider this modality and a negative patient perspective. The lack of practitioners trained in home dialysis, years of focus on in-center treatment models, and lack of patient understanding of the benefits of home dialysis will take time to overcome. Expecting these systemic changes within a few years is unrealistic and potentially devastating to many care providers.

Atlantic Dialysis Management Services is a for-profit, nephrologist-owned SDO operating 13 dialysis facilities in metropolitan New York City and Long Island. Six of the 13 dialysis facilities have mandatory inclusion in the ETC model. Three of the 6 facilities are in Queens County, New York, and 3 are in Nassau and Suffolk counties on Long Island. Only 2 of these 6 facilities currently offer home dialysis. Because the facilities included in the ETC

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model are independently owned and listed individually in the Medicare Provider Enrollment, Chain, and Ownership System, they are not eligible for aggregation under the current rules. In the past, this model allowed for greater independence and innovation among neighboring units while providing a safety net of common quality goals and economies of scale. It allowed for patient choice and allowed providers to have more voice in the way patients were treated, avoiding “one-size fits all medicine.” With the new ETC model, 4 of our facilities have to create new home dialysis programs quickly or incur significant financial losses when the Performance Payment Adjustment begins on July 1, 2022.

To incentivize dialysis facilities to increase home dialysis, CMS proposes Home Dialysis Payment Adjustment (HDP). All home dialysis treatments will receive additional payments on a sliding scale from 3% during the first measurement year (MY) to 1% in the third MY. HDP will phase out as of December 21, 2023.<sup>3</sup> We estimate that the HDP for the MY 1 would be around \$8 per treatment for us. This additional revenue would not be large enough to make the significant investments necessary to add new home programs to all clinics. State licensure issues, space availability to house the programs, lack of trained nursing staff, additional investments necessary for the equipment, and volume of patients needed to run these home programs efficiently are some of the concerns moving forward. The ability to run a multitude of home programs independent of each other in a financially responsible manner is particularly concerning. Performance Payments Adjustments are skewed heavily toward attaining achievement goals for home dialysis that are likely unrealistic for many dialysis providers, which makes it unlikely we will benefit from these incentives. Overall, these impending severe penalties as of July 1, 2022, overshadow the excitement of building a new, more holistic approach to patient care.

## CHALLENGES

### Coronavirus Disease 2019 Pandemic

The year 2020 was a watershed year for us. Even though we were aware of the coming ETC model, we were unable to prepare most of 2020 because of the coronavirus disease 2019 (COVID-19) pandemic, which hit New York City hard in the spring of that year and caused devastating damage to our operations for over a year. We hoped that CMS would delay implementing the model just as they did with the companion radiation oncology model. Instead, the model start and end dates, and the benchmark period

to measure the achievement and improvement scores, were changed. In our 6 facilities in the ETC model, an additional 71 patients died in 2020 compared with 2019, a nearly 65% increase in mortality, 82% of which were due to COVID-19 (Table 1). Disruption of safety net hospitals, primary care, and other services resulted in delayed referrals and a lack of planning opportunities for home dialysis and transplants during 2020. Since the benchmark year for the ETC model is July 1, 2019, through June 30, 2020, it is not hard to imagine COVID-19 pandemic will not negatively impact our initial performance and the years to come.

### Vaccine

During 2021, the start of the first performance year of the ETC model, the COVID-19 vaccine for our patients and the staff became available. Unfortunately, the difficulties in procuring the vaccine, lack of adequate supply, and a complicated distribution, administration, and storage system made it very difficult for many SDOs/IDOs to administer vaccines to large numbers of their patients and staff in a short period. This situation required a tremendous amount of resource and focus to overcome. The SDOs/IDOs frequently have fewer human resources in critical positions than their larger LDO counterparts. In times of crisis, this creates an allocation of resources conundrum, resulting in a disproportionately negative impact on SDOs/IDOs. We made the same choice that our fellow dialysis professionals made; to focus our attention on protecting the lives of our patients and staff. The tradeoff was to lose out on preparing for the ETC model.

### CLINICAL SUMMARY

- The ETC model promotes home dialysis and transplant by incentivizing programs that increase the use of these modalities.
- Owing to the lack of resources, SDOs/IDOs may be unable to start new home dialysis programs on time to take advantage of Performance Payments Adjustments beginning from July 1, 2022, which may negatively impact their financial performance.
- The negative impact to SDOs/IDOs may also result from the inability to aggregate, heavier weighting for home dialysis over transplant, and achievement over improvement.
- There are ways CMS could address ETC model concerns in final rulemaking to mitigate potentially disastrous effects on SDOs.

### Life during the COVID-19 Pandemic

While the COVID-19 pandemic raged in the city, our operational workload skyrocketed. We had to close some of our facilities and relocate the patients and staff to other locations. Health care-wide shortages of personal protective equipment were a significant concern. Most facilities worked with a skeleton staff, and the usual encounters with social workers and other professionals in the dialysis facilities and at other health care locations were drastically limited. Visitation to most facilities was not allowed, and meetings became virtual in an industry where personal interaction is key. The real-world implications of not being able to expedite home dialysis program projects, get staff to take certification examinations, and set up new sites inspected seriously impacted our ability to increase capacity. The concern over staggering patient losses made us very apprehensive about expanding at all. All these factors seriously hampered our ability to mount a robust response to the incoming ETC model.

**Table 1. Mortality Data for FFS Medicare Beneficiaries in the Current ETC Model for Atlantic Dialysis Management Services-Affiliated ETC-Enrolled Facilities**

Total Beneficiaries	As of December 31, 2019	1/1/2020-12/31/2020	1/1/2021-4/30/2021
Number of FFS Medicare beneficiaries	549	473	410
Number of FFS Medicare beneficiary deaths	110	181	35
Number of FFS Medicare beneficiary deaths due to COVID-19	N/A	58	0

Abbreviations: ETC, End-Stage Renal Disease Treatment Choices; FFS, fee for service; N/A, not available.

### Kidney Care in Flux

Since the beginning of 2021, CMS has introduced several new initiatives that will impact SDOs/IDOs and focus on the ETC model. Before January 1, 2021, ESRD beneficiaries were not allowed to join Medicare Advantage plans. Over 13% of our Medicare beneficiaries have switched to these plans since 2021, taking them out of the ETC calculations. Because enrollment for these programs is still open, the number of eligible FFS Medicare beneficiaries will fluctuate in the months to come. Other CMS payment model initiatives, such as Kidney Care First and Comprehensive Kidney Care Contracting, even though primarily affecting nephrologists, will potentially compete for our attention and resources too. These models do not share identical metrics or structures with the ETC model. In addition, they frequently involve the same patient populations and have a variety of incentives and penalties, which are different from the ETC model for the facility. While these 2 models are voluntary for a provider to enroll in, it is difficult to imagine why multiple models would be introduced at once, potentially forcing providers to choose between programs, rather than benefit from the proposed improvements of each plan. In the spring, CMS postponed the commencement of Kidney Care First and Comprehensive Kidney Care Contracting programs to 2022. From the perspective of SDOs/IDOs, participating in a wide variety of programs creates confusion and decreases the ability to comply with all requirements. The impact of these competing demands on the ETC model is difficult to forecast at this time, but it is hard to imagine it being a positive one.

### THE NECESSARY

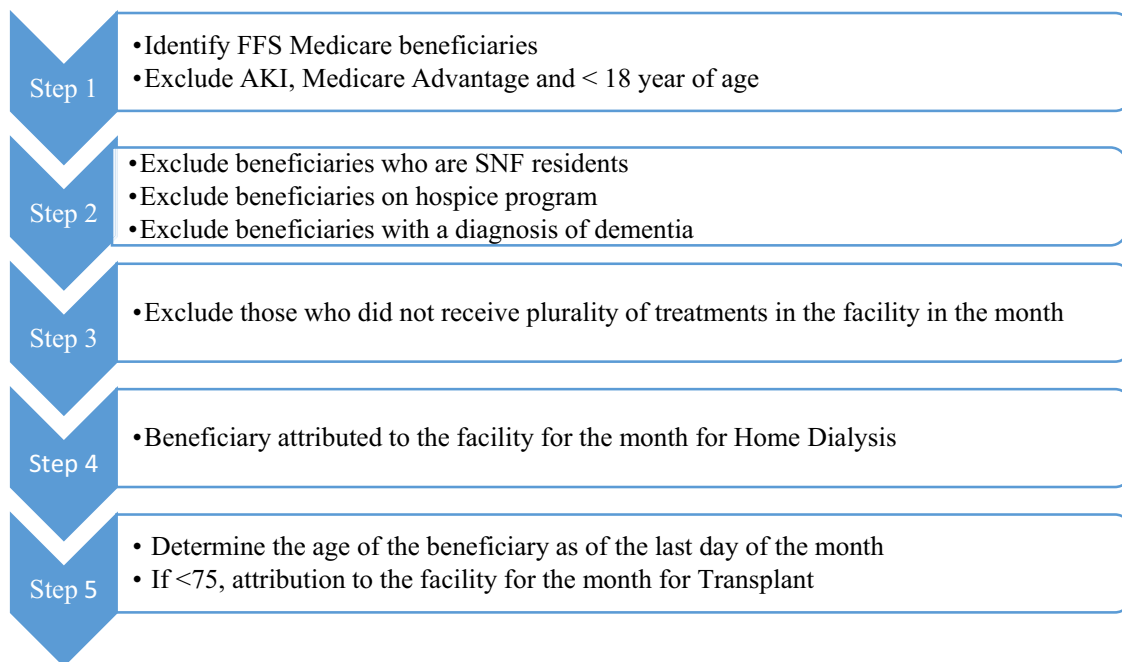
One of our priorities was to educate everyone on the new payment model. We conducted a series of educational webinars for the facility staff, including the administrators, charge nurses, social workers, and medical directors. Because nephrologists are also part of the new ETC model and their cooperation is vital to the success at the facility level, we arranged several webinars for the nephrologists and physician extenders to address their unique concerns. We also selected an administrative lead and a clinical lead to streamline our efforts.

Moving forward, the administrative lead will work closely with Revenue Cycle Management and Information Management Services to track the monthly FFS Medicare beneficiaries. Because the ETC model works

retrospectively, the administrative lead will use our five-step methodology shown in Fig 1 to determine the exact number of beneficiaries that will be attributed to the facility for the preceding month. This information is provided to the nephrologists, facility administrators, medical directors, and social workers to track the number of eligible beneficiaries for home dialysis, self-care dialysis, and transplant waitlist. In Table 2, we have shown the cumulative data for the first 4 months of the first MY for the 6 facilities in the ETC model in our organization.

This seemingly small undertaking brings up another concern for us: data. The flow of data from the ETC model to the facilities has been limited from the start. Many of us have struggled to identify the number of patients this would affect, our initial estimate of benchmarking scores, and other metric analyses. The limited nature of electronic medical records (EMRs) we used further complicates the matters. The dialysis-specific EMR that we use is not customizable to provide accurate reporting that can meaningfully guide ETC model decisions. Lack of meaningful EMR has forced us to invest in an information management team and other software solutions to begin to understand where we are starting from and maintain any prospective view of this experiment.

The clinical lead is responsible for organizing the existing home dialysis programs and working with local regulatory bodies to get approval for new home dialysis programs in the facilities that do not have a program. This person is responsible for reviewing and organizing the self-care dialysis program in all ETC facilities as 2 beneficiaries on self-care count as one home dialysis patient. The clinical lead is also responsible for encouraging nephrologists to be cross-credentialed at the facilities that offer home dialysis programs to increase patient referrals into existing programs. We are aware that some of our physicians have not used the home modalities recently, and we felt that a refresher course might be necessary. This refresher course will include mentored exposure to home modalities including Continuous Ambulatory Peritoneal Dialysis and Continuous Cycler Peritoneal Dialysis and home hemodialysis using newer equipment and Continuous Cycler Peritoneal Dialysis and home hemodialysis using newer equipment. Finally, the clinical lead will be actively recruiting registered nurses interested in making the transition to home therapies and exploring potential alternate individuals who might assist in these programs, such as licensed practical nurses and patient care technicians (Table 3).



**Figure 1.** Five-step methodology for the attribution of FFS Medicare beneficiaries to the ETC facility for a specified month. Abbreviations: AKI, acute kidney injury; ETC, End-Stage Renal Disease Treatment Choices; FFS, fee for service; SNF, skilled nursing facility.

## THE POSSIBLE

The self-care program is a potential area where SDOs/IDOs might mitigate losses because 2 self-care patients are counted equivalent to one home dialysis patient for scoring purposes. With 4 of our facilities that do not have a home program and no prospect of starting one in the near future, self-care dialysis may be the only way to get some relief on the improvement score on home dialysis to avoid penalties. However, currently there is no adequate definition of what constitutes self-care dialysis from the Federal or State department. In consultation with colleagues in the industry (C. Lowell, Dialysis Clinic, Inc, personal communication, March 22, 2021) and the local Department of Health, we have formulated policies and procedures that we hope will hold up to regulatory review and meet the reimbursement needs. The program will involve screening all dialysis patients for appropriateness and desire to perform self-care and training by specially trained staff. Fortunately, self-care dialysis training techniques are reasonably well defined in the literature. The training takes place alongside regular in-center dialysis patients using the same dialysis machines used in the facility. The dialysis machine is turned around and facing toward the patient. Patients are allowed to touch the machine, weigh themselves, wash their access area, and check their blood pressure, heart rate, and temperature. They report their current weight, the goal for the treatment, blood pressure, heart rate, and temperature to the staff for recording in the EMR. Patients will set up the machine every step until ready to start. At the end of treatment, they discontinue treatment and pull their needles, if possible. Self-cannulation of vascular access is not a requirement, but we will train if the patient is interested.

We have started the necessary paperwork to create 2 home dialysis programs in facilities without programs. Owing to regulatory hurdles with obtaining review and approval from the New York State Department of Health, we hope that this program will start sometime in the fall of 2021. In addition, we are actively pursuing another expansion of the existing home program, which could not start because of COVID-19-related emergency. Both these programs should be operational in 2022 (Table 3).

## THE IMPOSSIBLE?

On May 21, 2021, CMS updated the Achievement Benchmarks for MY 1 inclusive of January 1, 2021, through December 31, 2021 (Table 4). In preparation for implementing mandatory participation in the ETC model, we have taken necessary and possible steps to make this model work for us, but as the ETC model is structured now, it is doubtful that we will do well on the achievement scores for home dialysis. To succeed in this mandatory payment model, we need help from CMS and Center for Medicare and Medicaid Innovation (CMMI) in several areas. We believe that they have the tools to fine-tune the model by regulatory guidance and rulemaking.

1. *Random selection and skewed results:* CMS should reduce the number of facilities they have chosen for participation from any single provider group in the ETC model back to the original 30% of facilities to soften its impact on all our operations. We have nearly 50% of our facilities chosen for the model, and there are other small and independent dialysis organizations facing the same dilemma. We hope CMS will provide further guidance through the rulemaking process and to address this issue.
2. *To aggregate or not to aggregate:* With only 2 of our 6 chosen facilities offering home dialysis and little prospect

**Table 2. Categorization of Fee-For-Service (FFS) Medicare Beneficiaries Used for Benchmarking and Performance Rating Calculations in the Current ETC Model Rules for Atlantic Dialysis Management Services-Affiliated ETC-Enrolled Facilities From January 1, 2021 to April 30, 2021**

ETC Facility	A	B	C	D	E	F	Total
Total # of FFS Medicare beneficiaries	119	259	396	376	244	266	1660
# Of FFS Medicare beneficiaries after exclusions*	117	228	389	369	237	245	1585
# Of aligned FFS Medicare beneficiaries attributed to facility based on # treatments in the month† (denominator)	114	220	391	352	224	225	1526
# Of aligned FFS Medicare beneficiary months on home dialysis (numerator)	29	–	62	–	–	–	91
# Of aligned FFS Medicare beneficiaries younger than 75 y as of the last day of the month	83	122	238	308	176	159	1086
# Of aligned FFS Medicare beneficiaries younger than 75 y as of the last day of the month above those on a transplant waitlist (numerator)	43	8	70	64	69	34	288
Transplant eligible patients (denominator)	83	122	238	308	176	159	1086
# Of kidney transplants done	0	2	3	4	4	0	13
Living donor transplants	0	1	1	1	0	0	3

Abbreviation: ETC, End-Stage Renal Disease Treatment Choices.

\*Beneficiaries excluded because of skilled nursing facility (SNF), hospice, and dementia.

†Beneficiaries who received plurality of dialysis treatments in the facility and attributed.

of starting new dialysis programs in the near future, aggregating all 6 facilities into one group would be beneficial to avoid penalties. We would also like those facilities that do not have a home program to be allowed to retain the patients referred to a facility with a home program. This would allow us to concentrate on the intent of the program; to increase patients on home dialysis and offered home dialysis, rather than focusing on getting specific patients in specific areas into home dialysis.

3. *Equal weight for transplant:* As a result of our ESRD Seamless Care Organization participation, we significantly improved our cadaver and live donor transplant rates over the past 4 years. Our transplant waitlist among FFS Medicare beneficiaries is high, and it is frustrating to be penalized for past successes. In addition, it is difficult to significantly improve these rates in a metric that we have little control over and traditionally have referred to the specialists. We would like the policy on living donor transplants to be reviewed in rule-making. Giving equal weight to home dialysis and transplant waitlist achievement metrics would significantly help us and any care provider in a similar position because of ESRD Seamless Care Organization participation.
4. *Achievement vs improvement:* ETC model currently puts a lot more emphasis on achievement scores for home dialysis. An achievement score at the 90th percentile would bring in the maximum of 2.0 points, whereas there is no such option for an improvement score (Table 4). The 4 facilities within ADMS which do not have a home program currently will have no achievement score. Even if they were able to retain patients referred to a sister facility, it is unlikely the achievement

score would be significant enough to make us successful. However, by rewarding facilities that make significant strides to achieve the goals of the program, increase access to home dialysis, with an equally important improvement score, facilities would be motivated to work harder, rather than just accept the reality of their situation. In addition, the current model means that small facilities, similar to ours, are disproportionately punished for incidents out of their control (ie, patient' care partner expires so patient cannot continue on home therapy).

**Table 3. Summary of Steps Taken to Prepare for Success in the ETC Model**

Educate patients, staff, and providers about the ETC model and its components with monthly meetings
Name an administrative lead and define the role
Name a clinical lead and define the role
Create a corporate-level system to track beneficiaries and notify relevant staff of patients who are enrolled in the model
Designate members of information management staff to train and specialize in pulling, interpreting, and resolving ETC data
Design new home dialysis programs at centers that have none, including developing physical space, staffing models, and physician education/buy in
Submit applications for home programs and work with the Department of Health to get these approved
Cross credential MDs at multiple facilities to increase home dialysis referrals/participation at existing facilities
Develop a home dialysis refresher training course for MDs
Recruit and train RNs/LPNs/techs for home dialysis programs
Develop a policy and training for self-care
Begin to recruit staff and patients interested in self-care

Abbreviation: ETC, End-Stage Renal Disease Treatment Choices; LPNs, licensed practical nurses; MDs, medical doctors; RNs, registered nurses.

**Table 4. Proposed Scoring Methodology for Assessment of Measurement Years 1 and 2 Achievement Scores and Improvement Scores, Measurement Year 1 Achievement Benchmarks on the Home Dialysis and Transplant Rate in the ETC Model**

Achievement Score Scale for MYs 1 and 2	Points	Achievement Benchmark for MY 1-Home Dialysis Rate	Achievement Benchmark for MY 1-Home Transplant Rate	Improvement Score Scale for MYs 1 and 2
90th+ Percentile of benchmark rates for comparison geographic areas during benchmark year	2	28.18%	35.30%	Not a scoring option
75th+ Percentile of benchmark rates for comparison geographic areas during the benchmark year	1.5	18.33%	25.57%	Greater than 10% improvement relative to benchmark year rate
50th+ Percentile of benchmark rates for comparison geographic areas during the benchmark year	1	12.75%	18.34%	Greater than 5% improvement relative to benchmark year rate
30th+ Percentile of benchmark rates for comparison geographic areas during the benchmark year	0.5	6.83%	13.90%	Greater than 0% improvement relative to benchmark year rate
<30th Percentile of benchmark rates for comparison geographic areas during the benchmark year	0	N/A	N/A	Less than or equal to benchmark year rate

Abbreviations: ETC, End-Stage Renal Disease Treatment Choices; MY, measurement year; N/A, not available.

We firmly believe that a functioning kidney transplant or dialysis at home are the most ideal way to treat ESRD patients, and we laud the efforts of CMS to increase the percentage of patients who will be dialyzed at home and receive kidney transplant from either a cadaver or a living donor. However, we believe that the payment enhancements through HDPAs are too small to offset the investment of resources necessary to start new home dialysis programs in the facilities that do not have a program now, whether SDO/IDO or LDO. It is highly unlikely that CMS intends to drive the SDOs/IDOs out of the market because we bring tremendous value to the market. SDOs/IDOs frequently lead in developing innovative, cost-effective solutions for dialysis patients. We are able to personalize our approach to individual patient care, providing more of a “mom & pop” feel for medicine that is frequently missing in larger organizations. The ideas of individuals are more easily heard in SDOs/IDOs. Most importantly, the ideas and thoughts of patients are more easily heard in these organizations. It is not uncommon for our corporate executive management team to sit down with patients on the treatment floor to discuss issues. Many patients contact us directly, and our staff know us by name and face. That level of intimacy in health care is rare these days, and to price it out of existence would be a loss for all

stakeholders. While we, as an SDO, now focus on devising strategies to add small improvements to our scores with self-care dialysis programs, more home dialysis programs, and an increased focus on transplant, we hope CMS will consider the value of the SDO/IDO in the market and how to update the model to support their existence for years to come.

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