The questions below were received during the July 10 Dialysis Facility Compare National Provider Call. Questions were submitted to the Centers for Medicare & Medicaid Services (CMS) via the chat box and answered either over the phone during the webinar or subsequent to the webinar by CMS subject matter experts, as part of the question and answer commitment for the remaining submitted questions not answered during the webinar.

**Question:** Is it possible for peritoneal dialysis-only (PD) facilities to achieve a 5 STAR rating?

**Response:** Yes, it is possible for PD-only facilities to achieve a 5-star rating. The star rating is comprised of an average of three different domains, of which the Other Outcomes Domain 1 is excluded in the calculation of a PD-only facility's star rating. Thus, if a PD facility were to perform well in the two domains it is eligible for (Standardized Measures Domain and Other Outcomes Domain 2), then the average score of these two domains would be high and the facility could achieve a final score that would result in being assigned a 5-star rating.

**Question:** Many of the DFC measures are "standardized" but many are not. Have you considered the risk that non-standardized metrics may skew results based on local demographic variation?

**Response:** It is true that we use non-standardized measures. Typically, when we incorporate a non-standardized measure, it is because it's considered to be a part of a process in which there should not be variation based on something along the lines of local demographics. This is the same reason that for certain measures, such as dialysis adequacy, we don't incorporate methodological functions like risk adjustment into them. When we've made the decision not to standardize a measure, it's because we're operating under the belief that performance on the measure shouldn't be contingent on those kinds of factors. If you have a question about a particular measure, then we'd certainly be willing to discuss those on a one-on-one basis.

**Question:** Shouldn't you just consider if these new patients were referred to a transplant facility within the first year of being in dialysis?

**Response:** Although it is true that patient education and referral are important steps towards transplantation, there are practical hurdles currently to implementing measures based on referral due to lack of the necessary data captured at the national level. Beyond that concern, referral may be too low a bar for such measures as it is still quite distant from the goal of kidney transplantation. Studies have shown (e.g., Patzer et al, JAMA 2015;314:582) that only a minority of referred patients are ultimately waitlisted, and that there are racial disparities in the transition from referral to waiting. Dialysis facilities can contribute importantly to access to the waitlist beyond referral, such as assisting...
patients with completion of necessary evaluation studies and maintaining their health to help ensure candidacy.

**Question:** Why do we see a high number of Home Therapy stand-alone facilities with no Star Ratings?

**Response:** The reasons that we might see something like that is you have to qualify for at least one measure in each domain. And so, if you have a small number of patients or if you don't have enough patients to fit within the denominators of specific categories, then a facility may not receive a rating for that reason. Another reason may be simply that the facility is new, then the facility may not yet have adequate data in the performance period to receive a Star Rating even though it's already open and therefore reflected on DFC. So, those are two potential reasons which might explain why you see that. If you have a chance to take a look at the methodology and you think that doesn't explain why you're seeing that, then we'd certainly be interested in talking with you further about any concerns you would have.

If the question happens to be directed on the survey end, I'll just say that, for a patient to be eligible, we require that the dialysis treatments be in-center. And so, on our end, we exclude home-dialysis patients. Now, we don't exclude the whole facility because there's some facilities out there that serve a mix of home and in-center. For that type of facility, we don't want to be surveying patients on the in-center side. And so that particular facility would need at least 30 of those type of patients to be able to report it. If that facility primarily served the home-based crowd, then they would most likely be excluded.

**Question:** It's still not clear to me whether the Star Rating results that will be released in October 2019 will have the “reset applied.” Can you please clarify?

**Response:** A reset will not be applied for the October 2019 Star Rating Release. The October 2019 Release uses the same methodology first implemented in the October 2018 Release. For details please see the "Technical Notes on the Updated DFC Star Rating Methodology for the October 2018 Release" available at dialysisdata.org.

**Question:** Will DFC consider patients that have multiple comorbid conditions (trach, vent, carcinoma, etc.) and are on a staff-assisted home program?

**Response:** I'm not entirely certain whether or not this is intended to be a comment directly to the transplant measures. I think the answer is that where we have risk-adjusted for our various measures, we've attempted to adjust for patients' comorbidities. So, we don't necessarily risk-adjust for the fact that they have multiple comorbidity conditions, but if patients do have multiple comorbidity conditions, then these are typically captured in the risk-adjustment models that we have applied to our outcome measures. If this isn't quite what you're getting at with the question, then I would encourage you to submit clarification so that we can try to address that.
**Question:** What if you have a patient who has been reviewed and denied by the transplant team? Will they be carved out of the statistics?

**Response:** The way the measures currently work, these patients would not be carved out of the measure. I'm assuming you mean would they be excluded, or would the facility be given credit for that review? And the answer to your question is that, as they're currently constituted, the measures do not. The goal and reasoning behind this are that the facility will work with the patients to attempt to return for a review to be considered by the transplant team. And our hope is that the measure specifications will encourage this. We recognize that there is not going to be a state in which all patients are being waitlisted for these measures. And in fact, the performance distribution for the measures reflects that. So, I think we recognize that there are going to be some patients who aren't going to end up being transplanted. You're not expected to top out these measures at 100% -- well, ideally 100%. The short answer is, no, they're not carved out of the measures. And the reason for that is that we want to encourage the facilities to continue to work with patients to seek waitlisting where it is appropriate and possible.

**Question:** Given the new emphasis on home modalities when will you offer measures that will be sensitive to end-stage renal disease (ESRD) outcomes and quality for patients choosing home modalities?

**Response:** We've given a lot of thought to how to measure populations such as patients receiving dialysis at home, and there are some inherent difficulties. One of them is that the population is still relatively small, and that makes it difficult to develop quality measures that can meaningfully differentiate performance on them. On the other hand, we've undertaken a number of efforts that look into developing measures such as patient-reported outcomes that can reflect meeting patients' needs and expectations with dialysis that we think may have an opportunity to reflect this kind of concern. It's important to recognize that there are some inherent difficulties to developing measures that target this particular space directly. We are always interested in hearing ideas for what kinds of measures we could potentially develop in this area, and so we certainly welcome suggestions either through the help desk or reaching out to us directly.

**Question:** Are acute kidney injury (AKI) non-ESRD patients included in DFC measures?

**Response:** No, we are not currently including those patients within the denominators for our measures on DFC.

**Question:** Are quality incentive program (QIP) composites of quality consistent with Star Ratings?

**Response:** Despite differences in program goals, scoring methodology, and only partial overlap of metrics, DFC and QIP illustrate notable consistency in identification of dialysis facility performance. This is particularly true for poor performing dialysis facilities. As one might predict, DFC and QIP diverge on scoring of better performing facilities, based on differences in calculation methods that are generally
related to the very different needs and goals of the respective public reporting (DFC) and value-based purchasing (QIP) programs.

**Question:** Why aren't patients that have or had cancer excluded from transplant numbers?

**Response:** The Standardized Waitlist Ratio (SWR) adjusts for patients with cancers (based on Medical Evidence Form), as many patients with a history of cancer are still candidates for kidney transplantation. Both SWR and PPPW exclude hospice patients who usually have very limited life expectancy.

**Question:** When calculating transplant waitlist data is there any account for patients <65 y/o that have had transplants in the past but rejected and decline to go back on a list.

**Response:** No. However, I think what we don’t have within the measure is a capacity to capture if a patient has declined to go onto the list in the first place. So, no, we can't track whether or not they’ve simply declined to go back on a list. That's not something we currently have access to for the measures.

**Question:** In our area, we are a hospital-based outpatient clinic surrounded by 3 large, for-profit dialysis clinics. Looking at the data, our clinic treated approximately 800 patients over the last 3-4 years while the surrounding clinics treated less than 200 patients over the same time period. How is the Star Rating a fair comparison when the acuity is much higher in our patient population and we treat more patients versus the other clinics?

**Response:** Several of the DFC quality measures included in the star rating are risk-adjusted to account for patient case-mix, including prevalent comorbidities. In this way clinics with a similar patient-mix will be evaluated similarly on those individual quality measures. The quality measures included in the current star rating that adjust for patient risk factors are the following: Standardized Hospitalization Ratio (SHR) and Standardized Mortality Ratio (SMR) adjust for over 200 prevalent comorbidities, and a set of comorbidities at ESRD incidence; Standardized Transfusion Ratio (STrR) adjusts for certain comorbidities in the prior year associated with higher transfusion risk; the Standardized Fistula Rate (SFR) adjusts for a set of prevalent and incident comorbidities associated with lower likelihood of fistula use; and the Standardized Readmission Ratio (SRR) adjusts for a set of high risk conditions associated with higher risk of readmission.

**Question:** How does this effect a facility of <15 or <20 patients?

**Response:** I'm assuming that you're referring to the Star Ratings in this case. The answer actually relates back to the quality measures themselves. In order to receive a Star Rating, a facility must have at least one measure in each of the three measure domains that we developed for the Star Ratings. And so, the answer is that it depends upon whether the facility is meeting the case minimum thresholds for these individual quality measures. Those are themselves specific to the measures. That information can be found on DFC. If you follow up with the help desk, we can point you to that specific information with regard to the individual measures. The answer, though, is that if a facility doesn't meet those criteria for
the measures, then they simply are not given a Star Rating. They come up with N/A, and we indicate that the facility doesn't have enough power for us to be able to provide a meaningful assessment within the Star Ratings.

**Question:** Will CMS ever consider making a bell curve for those units who are not-for-profit to exclude those patients who are treated and have no way of paying or have been refused by all other units? These patients are typically the patients who have been shown to be not in compliance with medical care and therefore many times not meeting standard ratings. If the non-payment is a stressor for these units or they do not meet the standards, it is a double whammy for not-for-profit units, as then the reductions of payments usually follow, as well.

**Response:** Our program doesn't directly affect payments through reduction of reimbursement and the like. There is the ESRD QIP, which does this, but we're not in a position to answer for them one way or another. That said, your question is not irrelevant to what we do because of course the scoring can still have an impact, for instance, on the Star Rating that the facility is awarded. I would say this is not something that we have necessarily considered yet. It's also not something that's been suggested to us directly in terms of implementing a kind of a performance curve for this particular issue. I don't know that I can say clearly whether or not we would be willing to implement it. It would probably be something we'd have to sit down and think about. If you have a more formal or detailed suggestion that you'd like to submit to us, I would suggest submitting it to our help desk so that we can take a look. We would also be in a position to reach out to you just to seek out any clarification in terms of what you're looking for. Otherwise, I think the answer is that there needs to be more detail about what it is that you'd want to see before I could give you a clear answer.

**Question:** Where are the transplant data coming from?

**Response:** The data is obtained from the Organ Procurement Transplant Network (OPTN)/Scientific Registry of Transplant Recipients (SRTR) data source.

**Question:** Will consideration be made for patients who have been transplanted?

**Response:** When patients have been transplanted, they are pulled out of the denominator. There were some concerns raised during development of the measures and following our initial development phase that, for instance, higher rates of transplantation in a given area might lead to an artificially poor performance among facilities because their patients who were transplanted might be leaving the denominator faster, and as a result they don't get the benefit in their score of having those patients present. Obviously, we don't want to discourage transplantation of those patients. So, we did some analyses in response to those concerns, and what we found is that variations in rates of transplantation regionally don't appear to have any negative consequences for facilities for which they're being rated. Based on our analyses, we're confident that the measure is not going to unduly penalize facilities that are seeing their patients transplanted effectively.
**Question:** Is the transplant waitlist measure (PPPW) shown on DFC the exact same measure as the PY2022 QIP measure?

**Response:** The Measure to be used for QIP will be based on the measure in DFC. Specifics about scoring will be in the final rule.

**Question:** Will patients ineligible for transplant be excluded from the denominator? How do you identify the ineligibles for your data?

**Response:** The slides list out the exclusions for these measures, which you can find for the PPPW on slide 28 and for the SWR on slide 30. We've applied fairly broad exclusion criteria for these measures. The first and probably most prominent is that we've excluded all patients who are age 75 or older. And then we've excluded patients who are, depending on the measure, admitted to a SNF or hospice within a given month for the PPPW or who had been admitted to a skilled nursing facility (SNF) at dialysis incidence. This is intended to reflect that clinically the patient is unlikely to be a candidate for a transplant, as indicated by the fact that they've been admitted to a SNF or hospice. We've also incorporated within the SWR risk adjustments for age and incident co-morbidities to not exclude patients from the measure based on these, but to account for variation due to patient condition and comorbidity load. If you have any other questions with regard to how the measures are formulated, as we've noted, we've provided links to the measure documentation for these measures in the slide deck. I would certainly encourage you to review those. If you have additional questions about the precise specifications of the measures, then we'd certainly encourage you to reach out to us through the help desk and share your questions or concerns, and we can discuss them with you.

**Question:** Patients with emergency medical usually are ineligible for transplant, so how do you put these patients in the calculations?

**Response:** We believe the commenter is referring to Emergency Medical insurance coverage, which is a type of limited government insurance for undocumented aliens. The PPPW and SWR measures do not account for this status as an adjustment. The patient population for the SWR is selected based on the Medical Evidence Form. The PPPW requires dialysis patients remain in a facility as of the last day of the reporting month to be included in the denominator for that month.

**Question:** When patients have been determined not a candidate for transplant after evaluation due to medical comorbidities or removed from transplant list due to medical issues, why are they not be removed from the denominator of percentage for number of patients listed?

**Response:** We're intending the measures to encourage continued effort to seek waitlisting where possible. I think it's certainly reasonable to expect that there would be circumstances where it's highly unlikely that an individual patient is going to be waitlisted due to the presence of medical comorbidities. That's one of the reasons, for instance, that we risk-adjust for these in the risk model for the SWR. But it's also one of the reasons why we've incorporated the exclusions that we have for these measures, including placement in hospice of SNFs or for patients age 75 and older, where you're more likely to see
the presence of those kinds of medical comorbidities. We don't have exclusion criteria that fits specifically with a reason for rejection from the transplant, which we don't have access to, but rather we've excluded populations of patients from the measures that are more likely to encounter those kinds of circumstances.

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