End Stage Renal Disease Proposed Rule Analysis: A Missed Opportunity for Immediate Reforms to the DMEPOS Competitive Bidding Program

While there are positive, incremental policies within the proposed rule, CMS has arguably missed several opportunities to make real progress ensuring access for patients in need of critical durable medical equipment.

VGM will continue to provide feedback and encourages our membership of independent suppliers to submit their input via the comment process. VGM will provide members with templates to submit comments, similar to the Interim Final Rule with rural relief.

The following is a section by section analysis of the major provisions within the proposed rule.

1. **Proposal of Implementing "Lead Item Bidding"**

What it means - CMS proposes to expand its "lead item" bidding methodology, which now applies to a limited number of items that are prone to "price inversions," whereby the single payment amount (SPA) for an item with fewer features is higher than the SPA for the item with more features (e.g., non-powered versus powered mattress). Under these current rules, HCPCS codes for similar items with different features are grouped together and priced relative to the bid for the "lead item" – defined as the item in the grouping with the highest allowed services during a specified base period. Under the proposed rule, an expanded "lead item pricing" policy would replace the current bidding methodology. Suppliers would no longer submit a bid for each item/HCPCS code in the product category. Instead, the bid for the lead item would be the "composite bid" used to establish the SPAs for the lead item and all other items in the product category. The lead item would be identified based on total national allowed **charges** rather than total national allowed **services**. CMS would make conforming changes to CBP rules to take into account the lead item bidding, and the agency expects to split some of the larger "conglomerate product categories" under this proposal.

Pros – VGM is supportive, in general, of lead item pricing throughout the bidding process. This will allow for a simpler bidding process for suppliers wishing to submit a bid. Rather than bidding on dozens of individual items for a piece of equipment, the supplier would bid on the entire item.

Cons - CMS will determine, as it did previously, the percentage of each individual part of the equipment. The devil is in the details as suppliers have little transparency to determine payment amounts for these additional items. A primary example of this would be accessory items on wheelchairs, where suppliers deserve transparency on how these prices will be set.

2. **Adjustments to DMEPOS Fee Schedule Amounts Based on Information from the DMEPOS CBP**

- Items and services furnished on or after Jan. 1, 2019, in areas that are currently CBAs, CMS would adjust the fee schedule amounts based on the SPAs in effect on the last day before the CBP contract periods of performance ended, increased by the projected percentage change in the Consumer Price Index for all Urban Consumers (CPI–U) for the 12-month period on the date after the contract periods ended. If the gap in the CBP lasts for more than 12 months, the fee schedule amounts would be increased annually on the anniversary date of the first day after the contract period ended based on the projected percentage change in the CPI–U for the 12-month period ending on the anniversary date. However, payment for non-mail order diabetic testing supplies would continue at the current SPA rates for mail order diabetic testing supplies until new rates are established under the national mail order program (i.e., they would not be updated for inflation).
- Items and services furnished in 2019 or 2020 in areas that are currently not CBAs, that are rural areas or not located in the contiguous U.S. — CMS would extend through Dec. 31, 2020, its current methodology that bases fee schedule amounts on a blend of 50% of rates that are adjusted to take into account CBP pricing information and 50% of unadjusted fee schedule amounts.
- Items and services furnished in 2019 or 2020 in non-CBAs that are not rural or non-contiguous areas – The fee schedule amount would equal 100% of the adjusted payment amount. CMS requests comments on whether the 50/50 blended rates should apply to these areas as well.

What it means – As noted, beginning Jan. 1, 2019, there will be three different methodologies, depending on the area in which a patient resides. Because CMS has not announced a 2019 competitive bidding program, some rules have changed ***until a new round of bidding begins.*** VGM estimates that the most likely scenario is a new program effective Jan. 1, 2021. This would likely require the onset of the RFB (instructions, et al) sometime in 2019.

- **Within a competitive bidding area:** Any enrolled supplier can provide equipment to patients who reside in a competitive bidding area. The items will be paid at the current single payment amount (SPA) with the percentage addition of CPI-U (in layman's terms, this is to account for inflation, which would only translate to approximately a 1.5% increase the following year). For those with a current contract, it appears you will be off the hook for accepting Medicare patients if you choose.

    - **Pros** – Suppliers who wish to exit the program or new suppliers wishing to participate in the bidding areas may do so.

      Note: It is VGM's position that suppliers will have the ability to bill non-assigned, because there will no longer be the same contractual obligations that came with bid winner requirements.

- **Cons** – Competitive bidding SPAs were set with the assumption that suppliers could make up the lower reimbursement by a higher volume in patients. By shifting to any willing supplier, it removes the potential volume of new patients coming through a supplier's door. This also is not fair to contracted suppliers who have shifted their business models, based on multiple rounds of bidding, while having to accept the lower reimbursement. Without CMS rolling out a bid program every three years, as it is required by law, with the announcement suppliers have no long-term stability in making business decisions.

- **Non-Rural, Non-Bid areas receiving the adjusted fee schedule level**

  - What it means - These are the smaller metropolitan, densely populated areas. Patients in these areas fall under the "100% adjusted" amount. This means these areas see no additional reimbursement increase, other than the current rates. In this section, unlike the competitive bid areas, there is no mention of a CPI-U (inflation) adjustment. VGM has been vocal about what CMS considers "rural," and this is a major area where the rule falls short. We'll continue to argue for a full application of the blended rate to all non-bid areas. CMS is also soliciting comments to consider expanding this and would be effective "on or after Jan. 1, 2021." The 21st Century Cures Act mandated that stakeholder input of all non-CBA areas must be taken into account regarding the establishment of prices, which appears to have been largely ignored in this proposed rule.

  - **Pros** – There is an opportunity for comments as CMS is seeking public input from the supplier community on this proposal. Suppliers must share how unsustainable this adjusted rate is for patient accessibility for this equipment.

  - **Cons** – The current reimbursement rates for all suppliers are set in an extremely flawed way, which has driven CMS to make a change for rural and non-continuous suppliers in order to protect patient access. With reimbursements set to remain at the current "adjusted rate" (July 2016 levels), suppliers will still face the near impossible task of providing quality care for their patients. This is especially the case for oxygen suppliers who face the "double dip" on oxygen equipment with budget neutrality pushing rates below CBA oxygen rates, which is addressed later in this analysis. Specifically left out of this change were non-rural, non-bid suppliers, which includes smaller cities and the surrounding areas. The method that CMS uses to determine rural and non-rural is highly flawed as it is based on a computer calculation for population rather than the real-world feedback given by suppliers of the longer-distance areas that they serve. With approximately two-thirds of the population living in these areas, a lot of patients are excluded from this effort to increase patient accessibility by CMS. CMS is

continuing to accept comments on this issue, which we will be pushing hard with policymakers to fix this harmful exclusion until more reforms are made to the program.

- **Rural and non-contiguous areas will receive an increase in reimbursement through 2020.**
  - **What it means** - For patients residing in a rural or non-contiguous area, suppliers will see an extended increase of the "blended rate," which is where CMS is currently paying, thanks to relief of the interim final rule back in May. This increase is effective from Jan. 1, 2019, through Dec. 31, 2020. This maintains rates at the January 2016 levels when the first cut took place.

  - **Pros** – VGM is very happy to see this acknowledgement from CMS that there are patient access issues due to the extremely low reimbursement rates that were derived from urban, densely populated suppliers. This will allow suppliers to provide patients in some of the most remote areas with equipment they need to remain in the comfort of their own homes instead of a costly facility. With rates moving to the "blended rate" (January 2016 levels), suppliers have some more room to breathe and prevent many from closing their doors. Another positive point is that this change is extended, at minimum, until Dec. 31, 2020.

  - **Cons** – Until a new program is conducted with additional reforms, suppliers in these areas as well as non-bid areas are subject to the highly flawed bidding rates.

3. New Payment Classes for Oxygen and Oxygen Equipment and Methodology for Ensuring Annual Budget Neutrality of the New Classes

What does it mean – This will establish a new product class for liquid oxygen products. Payment classes for portable liquid oxygen, portable gaseous oxygen, and high-flow portable liquid oxygen have been added. This will come into play in the next round of bidding, so no rate changes for the time being on these items.

Pros – The separation of liquid oxygen classes acknowledges the large difference between providing liquid vs. stationary oxygen.

Cons – VGM is seriously concerned that the proposed methodology does not address the significant costs associated with delivering this life-saving equipment. Suppliers needing to deliver this equipment at least twice a month are going to be severely limited when it comes to servicing the patient properly. With the added costs such as a commercial driver's license and hazmat labeling, the current payment methodology does not meet the costs associated with providing liquid oxygen. Additionally, CMS has doubled down on the authority to artificially

reduce oxygen rates by applying an outdated budget neutrality regulation to oxygen equipment. Lastly this language only addresses portable liquid oxygen, not stationary liquid oxygen tanks.

4. Payment for Multi-Function Ventilators

What does it mean – Within the ruling for the multi-function ventilator, there is consideration to put the device under one payment category: the frequent and substantial servicing payment category. This is the payment category that is a continuous rental but also includes accessories, maintenance, and repairs. CMS is seeking comments as far as the coverage criteria because there are five different medical policy requirements to meet for reimbursement. For example, let's say a patient meets the qualifications for the ventilator, cough assist, and suction but does not need the oxygen or the nebulizer. The supplier would get reimbursed for three of the five devices, not all five. On top of that, the only FDA-approved multi-function ventilator is likely an expensive medical device.

Pros – The ventilator does provide both invasive and non-invasive options. The nebulizer, suction, and cough assist seem to provide adequate pressures and functions. The oxygen function works like a portable concentrator providing up to 6lpm (40% FiO2) at a pulse dose setting. This particular function means that it's designed for a specific type of patient population. With the POCs that are on the market, patients have to be tested to ensure the device works for their condition, being the only FDA-approved device, the VOCSN would need to be considered in the same manner.

Cons – The issue with the current competitive bid program is that the patient would have to use several different suppliers because most suppliers would not have all the contracts. While ventilators, suction machines, and cough assists are not part of competitive bid, oxygen and nebulizers are competitive bid items under separate categories. Depending on the supplier, the patient could essentially have to use five different suppliers to get the proper care and medical equipment as prescribed by their physician. Imagine dealing with five different suppliers as a patient or a physician, or even being one of those five suppliers. Sounds like a disaster waiting to happen.

5. Including the Northern Mariana Islands in the Future Mail Order Program

What does it mean – Beginning on or after the date that contracts take effect for a national mail order program, the Northern Mariana Islands will be included in the program.

Pros – None.

Cons – This proposal demonstrates that individuals at CMS believe that the competitive bidding model is working. Rather than beneficiaries having the ability to choose a local supplier, they will continue to be forced to receive their supplies from companies from miles away, being subject to the mail. This is an especially large problem in the case of natural disasters where the mail could likely be held or delayed, potentially forcing patients to scramble for supplies. The

national mail order program has caused a decrease in the number of test strip manufacturers, stifling future innovation. Lastly, with this expansion, CMS has not addressed the decrease in patient utilization with this program and forcing patients to pay out of pocket.

Conclusion

These are the major provisions within the ESRD, which contains proposals for modifying the competitive bidding program. While CMS is calling this "modernizing" the DMEPOS program, disguising it as an overhaul, VGM believes that this was a missed opportunity for major regulatory reform to strengthen access to DME in urban, non-rural, and rural areas across the country. In reality, while the competitive bidding program is inevitably delayed until CMS conducts another round of bidding, they have effectively extended the current program. With no indication of when the next program will be, which is one of the few methods of pushing prices upwards for this equipment, it could be a few years before a new round is conducted. The status of the industry right now is not acceptable, as suppliers are at the mercy of CMS to make these crucial changes.

Supplier Action Items

All of these items are under a proposed rule, which CMS is required to take into account public comments prior to issuing a final rule. It is imperative that CMS sees an overwhelming wave of demand for immediate policies which provide sustainable reimbursements to suppliers, not years from now when a new round of bidding is conducted.

It is critical suppliers submit comments as soon as possible for this proposed rule at regulations.gov, *Medicare Program: End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program and Fee Schedule Amounts, etc.*

Because of a short comment window of less than 60 days, suppliers must act quickly to have comments submitted by the week of Aug. 20. This is to ensure that CMS sees comments right away, as this will be a tight turn around for when they issue a final rule on these proposals. **The deadline for comments is officially Sept. 10.**

VGM will be here to assist and provide feedback to suppliers offering input. VGM will continue to utilize every tool possible in order for suppliers to receive the proper reimbursement necessary to provide the quality care that beneficiaries deserve.