CQRC COUNCIL FOR QUALITY RESPIRATORY CARE

April 6, 2017

Seema Verma, MPH
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Request for Stakeholder Input on Adjusting the DMEPOS Modified Fee Schedule

Dear Administrator Verma,

On behalf of the Council for Quality Respiratory Care (CQRC), I want to thank you for providing us with the opportunity to share additional information related to the cost of furnishing home respiratory therapy items and services (*e.g.,* home oxygen and sleep therapies) to Medicare beneficiaries in non-competitive bidding areas (non-CBAs). The CQRC is a coalition of the nation's seven leading home oxygen and sleep therapy providers and manufacturing companies. Together we provide in-home patient services and respiratory equipment to more than 600,000 of the more than one million Medicare beneficiaries who rely upon home oxygen therapy to maintain their independence and enhance their quality of life. Similarly, we provide homecare services, equipment and supplies to more than one million Medicare beneficiaries with Obstructive Sleep Apnea (OSA).

As a threshold matter, we appreciate the outreach to stakeholders to seek information on the three specific questions outlined in the notice. To that end, we have quickly surveyed our supplier membership to provide you with specific answers to these questions. However, we also encourage the Agency to develop a statistically appropriate tool for assessing the cost of providing services on an ongoing basis. For too long, the industry and the Agency have spoken past each other using different data and analyses. As with other health care providers, the data from such a tool should be de-identified and made available to allow interested parties to analyze it as well to promote transparency and create a common understanding of the cost of providing items and services. As we have discussed with your staff many times in the past, we agree that reimbursement rates should reflect the cost of providing services. The current rates simply do not.

Additionally, we continue to recommend that CMS develop a cost-based methodology that is informed by the results of the competitive bidding program rather than apply the competitive bidding area (CBA) rates to non-CBAs. Yet, we understand that it may take more than a single rulemaking cycle to address this concern. Thus, in the meantime and based on the information provided in this and our previous comment letters, we recommend that CMS better align the Modified Fee Schedule rates with the cost of providing items and services by (1) refining the

adjusters in the Modified Fee Schedule and (2) modifying the competitive bidding methodology. Finally, we also ask that, consistent with our previous letters, CMS address the inappropriate application of the budget neutrality factor for oxygen concentrators, implement the Congressionally mandated extension of the phase-in using the blended rate that applied January 1 – June 30, 2016, and further extend the phase-in period for the new Modified Fee Schedule until the next round of competitive bidding takes place.

I. The Cost of Providing Home Respiratory Therapy Items and Services in Non-CBAs Is Higher than It Is in CBAs.

As data shared with CMS from the CQRC companies in 2014 showed, the cost of providing services in non-CBAs was 13 percent higher than the costs in CBAs, on average. This cost survey also showed that the costs in areas defined by CMS as "super-rural" under the Ambulance Fee Schedule were on average 17.5 percent higher than those of CBAs, while the costs in areas defined as "rural," again under the Ambulance Fee Schedule definitions were 11 percent higher. In addition, this survey found that the actual cost of providing services in CBAs on average were 5 percent higher than the average Single Payment Amounts (SPAs) used in the CBAs, showing that the SPAs are below the cost of providing items and services even in the CBAs. Thus, the total amount that the SPA rates are below the cost of providing services in non-CBA areas for CQRC companies is 18 percent. This survey focused on the national and large regional home respiratory therapy suppliers who are members of the CQRC. Given their efficiencies and economies of scale, we anticipate that if a similar survey were conducted of all home respiratory therapy suppliers, the costs would be somewhat higher.

We understand that it may seem counter-intuitive to assert that the cost of providing items and services in rural areas is more expensive than in the competitive bidding (urban) areas. However, as the data below demonstrates, the fact is that costs are higher in non-CBA. There are four primary reasons for these higher costs.

- **Mileage between supplier and beneficiaries' homes is greater in non-CBAs than in CBAs.** The distance between beneficiaries' homes and the supplier is significantly greater in rural areas when compared to urban areas, which increases the amount of fuel required, as well as the time spent to provide the services. For example, one member company operating in Georgia provides services to beneficiaries in a rural area that extends 98 miles from the supplier's location. It can take the employees one-and-a-half hours to visit the various beneficiaries in this area, resulting in travel that averages approximately 250-300 miles a day. Montana is another example of where an average in-home delivery may be located 110 miles away from the supplier's location. A recent set up in

Moberly, Missouri, required the supplier to travel 270 miles. Another example demonstrates that rural terrain also complicates matters. For at least one CQRC supplier providing equipment and services in rural Colorado, the mountains complicate delivery. A 60-mile trip can take an hour and half to two hours in good weather, and much longer during the winter snows.

- **The number of beneficiaries receiving items and services is lower in non-CBAs than in CBAs.** In other payment systems, CMS recognizes that low-volume providers have higher costs. The same is true for home respiratory therapy suppliers. There are simply fewer patients over which to allocate the fixed costs of providing services. These include costs such as rent, utilities, licensing, information technology infrastructure, financial/accounting, compliance, and employee wages. In more densely populated CBA markets, suppliers can cover their fixed costs with a lower per beneficiary rate than in a non-CBA. According to the 2017 CQRC survey of our supplier members, the number of patients served in CBAs is at least 74 percent greater than the number of patients served in rural areas.

- **Providing the same services in some non-CBAs requires more staff than in CBAs.** Population density also impacts the number of employees that a supplier must have in order to provide the same level of services in a more densely populated CBA. Suppliers are required to meet a set of minimum service requirements, such as a minimum of 30 office hours as and ensuring that certain professionals are on-call for beneficiaries 24/7. In some areas where the distances are great, additional service providers, drivers, or clinicians are required to ensure that beneficiaries have access to these services when needed. With fewer patients per employee in rural areas, higher revenues per beneficiary are needed to cover the cost of providing services.

- **Bureau of Labor Statistics (BLS) data show fuel and health care expenditures are higher in rural areas.** The most recent data available from the Bureau of Labor Statistics (2015) show that household expenditures for fuel costs and health care costs are higher in rural areas. For example, rural households spent $2,313 on gasoline and motor oil, compared with the $2,068 spent by urban households.[1] These data points mirror the experience of suppliers as well.

Both the Congress and CMS have traditionally recognized the increased cost of providing services in rural areas and established rural adjusters. We appreciate

[1]https://www.bls.gov/cex/2015/combined/tenure.pdf.

that CMS provided a rural adjuster to the Modified Fee Schedule as well. We remain concerned, however, that this adjuster as currently specified is not sufficient. Therefore, we appreciate the data points outlined in the 21st Century Cures Act as a starting point to reassess the Modified Fee Schedule amounts and the adjuster. While we believe a more detailed cost survey conducted in a reasonable period of time would provide more precise answers to the questions CMS has posed, the timeframe provided did not allow the CQRC to undertake such a survey.

A. Answers to CMS Questions

1. Average travel distance and costs associated with furnishing items and services in an area.

As noted above, the distances traveled in non-CBAs are greater than those traveled in CBAs. The CQRC survey data demonstrates this fact. Nationwide, the 2017 CQRC survey found that the distance traveled in rural areas is approximately 64 percent higher than the distance traveled in CBAs.

2. Average volume of items and services furnished by suppliers in the area

We assume that this question seeks to learn more about how fixed costs and staffing can be spread over the number of beneficiaries in an area. Overall, the 2017 CQRC survey of members found that there are approximately 74 percent more home respiratory therapy patients being served in CBAs when compared to rural areas.

3. The number of suppliers in the area

As CMS's own data shows, the number of suppliers across the country has substantially decreased since the implementation of the competitive bidding program. While CQRC members provided their best estimate of suppliers in the non-CBAs versus the CBAs who are actively furnishing items and services to Medicare beneficiaries, we believe that the claims data to which CMS has access provides a more accurate picture. To that end, we have also provided a snapshot based on the 2014 Durable Medical Equipment Public Use File (DME PUF) and analysis by The Moran Company to answer this question. Based on this analysis, The Moran Company found that in 43 percent of rural areas (as defined under the Modified Fee Schedule), Medicare beneficiaries have access to only one or two home oxygen therapy suppliers. In 35 percent of the rural areas, beneficiaries' choices are also limited to only one or two suppliers for home sleep therapies.[2]

[2]The Moran Company, Number of Billing National Provider Identifiers (NPIs) by Supply Category (Mar. 2017), *available upon request.*

B. CQRC Recommends Increasing the Rural Modifier and Adding a Non-CBA Adjuster to Reflect the Higher Cost of Providing Items and Services in all non-CBAs.

Based upon the previous CQRC cost survey and the information provided in response to the questions CMS has asked, the CQRC recommends that the Agency increase the rural adjuster that is part of the Modified Fee Schedule to at least 20 percent, if the Agency retains a single adjuster. While this amount is based on 2014 data, it accounts for the on average 13 percent higher non-CBA costs when compared to those in CBAs and the 5 percent differential between the CBA rates and the cost of efficient suppliers providing services in the CBAs. It also takes into account the fact that smaller suppliers may have slightly higher costs than the CQRC members. However, this analysis and recommendation are based on CBA rates that have once again been reduced in more recent competitive bidding cycles and, thus, the 20 percent likely no longer reflects the actual difference between the current rates and the cost of providing the equipment and services to beneficiaries.

Additionally, while we greatly appreciate the Agency's decision to extend the definition of "rural" to more than the original handful of States, as the CQRC data demonstrate, this definition remains too narrow. The higher costs suppliers experience is not only in areas defined as rural. These higher costs are true across all non-CBA ZIP codes. Therefore, we ask that as long as CMS applies the regional SPA to non-CBAs that it also provides a non-CBA adjustment separate from the rural adjuster that applies to all items and services provided in non-CBAs. Then, the rural adjuster would be added for those non-CBA ZIP codes that meet the definition of rural in current regulation. The CQRC would welcome the chance to work through the interaction of two adjusters with the Agency.

Over time, we recommend that CMS shift away from applying the average SPAs to the non-CBAs and collect cost data to determine the appropriate fee schedule amounts. The CQRC would be pleased to work with CMS on developing such an approach.

II. CQRC Recommends that CMS Revise the Competitive Bidding Program Before the Next Round of Bidding Occurs.

Finally, we ask that CMS also revise the methodology used to set rates in the competitive bidding program. While it is important to get the rates right for CBAs, it is even more critical if these rates are to be applied with adjusters in non-CBAs. The CQRC appreciates the willingness of the Agency staff to engage with us during the last several months to develop recommendations for changes to the competitive bidding program that could take effect for the next round. While we have and will continue to provide additional background on our recommendations, we thought it

would be helpful to include the general recommendations as part of this letter to emphasize the importance of making such changes as they relate to setting the Modified Fee Schedule rates as well.

In brief, the CQRC recommends that CMS:

- **Split the current oxygen and sleep product category**. Home oxygen and home sleep equipment and services are distinct types of products that should be bid as such. While we understand that some beneficiaries rely on both types of therapy at the same time and it may seem more convenient for them to receive the products from the same supplier, the result of combining the two product categories into one has been to allow suppliers providing only one product type to deflate the rate for the one they do not provide. We believe that separating oxygen and sleep into separate product categories will increase competition on the sleep items and services.

- **Replace the median methodology with a clearing price methodology for setting the rates**. As the CQRC and others have recommended, it is time for CMS to replace the median methodology because it has allowed low-ball bidders to artificially lower the rates being set and left legitimate suppliers with the choice of accepting rates sometimes far below their bids or not participate in a market for 3 years or more. Shifting to a clearing price methodology would significantly help in addressing the low-ball bidder problem.

- **Do not use inexperienced supplier data in setting the clearing price.** Another concern with the current methodology has been that inexperienced suppliers are weighted too heavily in the process and can also result in rates being driven downward inappropriately. While we support providing opportunities for new entrants to participate in CBAs, we would like to reaffirm that CMS plans to set their capacity at zero so that their bids are not used to set the rate in a clearing price methodology. Similarly, only the historical capacity for suppliers who have provided the items and services in the specific product category in the specific CBA should be used in determining the rates in that product category and when determining capacity for meeting demand.

- **Eliminate composite bids and rely upon a percentage of the 2015 DME Fee Schedule.** If CMS does move to a clearing price methodology, it will need to adjust the bidding process to focus bids on a single product. While this can be done in different ways, the CQRC recommends that CMS ask bidders to bid a percentage off of the 2015 fee schedule rates.

An alternative is to designate a lead product for each product category, which is what CMS has already done in a limited instance. This option, while potentially mathematically equivalent to the percentage off of the 2015 fee schedule, is more difficult to implement because it requires proposing and obtaining comments on a lead product, as well as setting the proportional relationship between the lead product and the other products in the category. This flat fee bid approach avoids having to go through such a process.

- **Enforce the physical presences requirements related to State licensure.** As the Office of the Inspector General reported, there have been problems with confirming that winning bidders are appropriately licensed in the States in which they have won bids.[3] It is extremely important to ensure that winning suppliers are licensed in the States in which they provide services, consistent with current statutory and regulatory requirements. Part of maintaining a license for a home respiratory therapy supplier in many States requires the supplier to maintain a physical presence in the State. Tennessee is one example of such a State. Therefore, we ask that CMS emphasize that when State law requires a supplier to have a physical presence to be licensed in the State, the supplier must demonstrate when bidding that it has such a physical presence. We also recommend that for home respiratory therapies, CMS enforce the quality standard that requires a physical presence.

We encourage the Agency to implement these refinements prior to the next round of competitive bidding. Doing so will also have an important impact on the Modified Fee Schedule rates and the adjusters.

III. CQRC Recommends that CMS Refrain from Launching the Sleep Bundling Pilot.

The CQRC remains deeply concerned about CMS's effort to launch a sleep bundling pilot. There appears to be no disagreement on the value that high-quality home sleep therapy provides Medicare beneficiaries who can medically benefit from such equipment and services. These benefits are threatened, however, if multiple policies are applied at the same time without having a full evaluation of the impact of each policy individually. As we have noted in the past, the goals of bundling include reducing overall costs to the program and driving efficiencies within a group of providers or suppliers. However, those are the same goals attributed to implementing the competitive bidding program. While achieving these goals may be laudable, implementing two different policies to achieve the same goals seems inappropriate and unnecessary. Additionally, we have raised questions about

[3]OIG, "Incomplete and Inaccurate Licensure Data Allowed Some Suppliers in Round 2 of the Durable Medical Equipment Competitive Bidding Program that Did Not Have Licenses," (May 2016).

whether the rationale outlined for implementing bundling is supported by the actual data on repairs and supplies. Even if the rationale supported implementing a pilot, the lack of detail on design features, such as case-mix adjusters, geographic adjusters, and other standard elements of a bundled payment system, make it difficult to understand how the bundled rate would be appropriately balanced to ensure that high-cost patients continue to receive the items and services they medically require.

We have provided detailed analyses in previous letters and plan to provide additional follow-up information to CMS as well in the coming days, but raise the issue in this letter to highlight the importance of taking a measured approach to implementing policy changes in the area of home respiratory therapy generally and home sleep therapies in particular.

In brief, we ask that before CMS pursues the home sleep therapy bundling pilot, it establish a more sustainable Modified Fee Schedule and implement the changes we recommend regarding competitive bidding before the next round takes place. Once the impact of these changes are evaluated, especially the separation of the home oxygen and sleep therapies into different product categories, CMS and stakeholders will be able to determine if the rationale the Agency has articulated for introducing the bundling pilot supports doing so in light of these other policies.

IV. Conclusion

The CQRC appreciates the opportunity to provide additional information to CMS about the Modified Fee Schedule and the questions presented by the Agency. We would welcome the opportunity to talk with you and your team about how to improve the Modified Fee Schedule and competitive bidding in more detail. If you have questions or would like to speak with our members, please contact Kathy Lester at (202) 534-1773 or klester@lesterhealthlaw.com.

Sincerely,

Dan Starck
Chairman, Council for Quality Respiratory Care

cc: Laurence Wilson, Director, Chronic Care Policy Group
Jeanette Kranacs, Deputy Director, Chronic Care Policy Group
Joel Kaiser, Director, Division of DMEPOS Policy