Interpreting & Preparing for the 2019-2021 Proposed Rule Changes

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Presented by:

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As attendees are most aware

- On May 9, CMS released information pertaining to an "interim final rule" (CMS-1687-IFC) that the industry was anxiously awaiting since August 2017
  - Increased fee schedule rates from June 1, 2018 through December 31, 2018 for DME and enteral nutrition to the "blended" 50/50 formula
  - Only applied to rural and non-contiguous areas (Alaska, Hawaii, and U.S. territories) of the country

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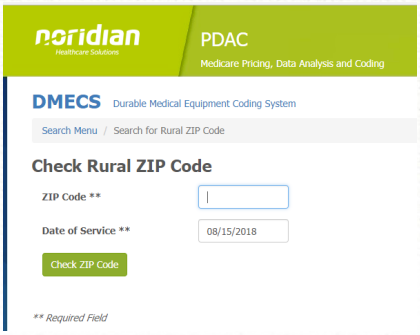
Rural Zip Code Checker

- https://www.dmepdac.com/dmecsapp/RuralZipCode/Search



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The Concern

- Texas has many “Micropolitan” areas such as Laredo, Corpus Christi, Amarillo, etc.
- These areas and surrounding communities are considered suburban (non-rural) by CMS standards
- While 71% of non-CBA zip codes are considered “rural,” only 21% of the population resides in these areas, which shrinks the scope of the relief
  - Scope was narrowed from all non-CBA areas ostensibly due to significantly higher costs

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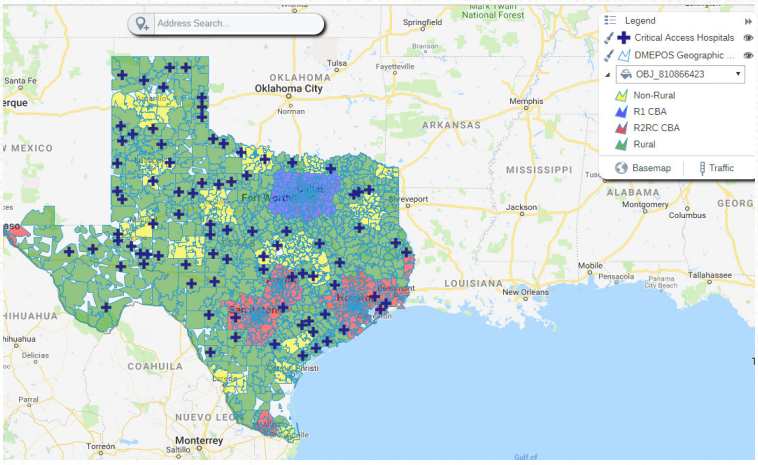
Texas Geographic Classifications



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Perhaps a better example?

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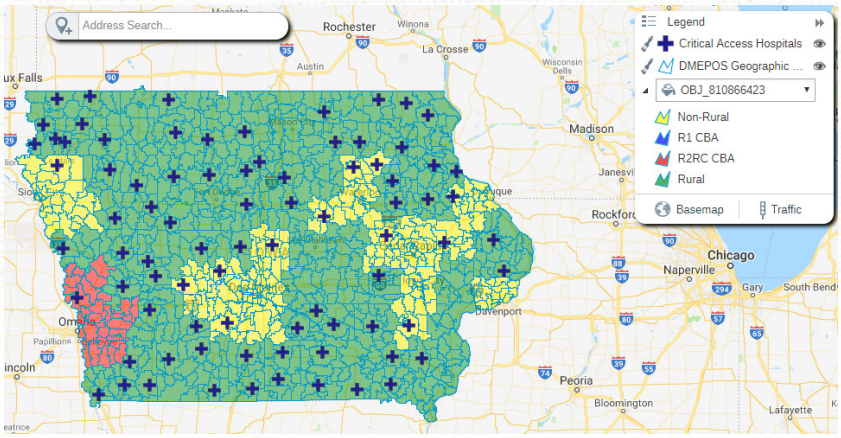
Iowa



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CMS appeared to recognize some issues supported by the industry

- "Today's action aims to protect access to needed durable medical equipment in rural and non-contiguous areas that are not subject to the DMEPOS CBP, helping beneficiaries to maintain their health, mobility, and overall quality of life. Stakeholders have raised concerns about significant financial challenges the current adjusted DME fee schedule rates pose for suppliers, including many small businesses, and that the number of suppliers in certain areas continues to decline."

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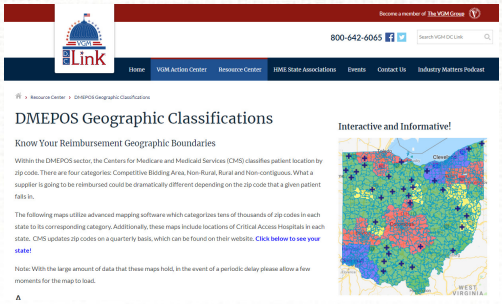
Find Your Maps on VGM D.C. Link

- http://www.vgmdclink.com/resource-center/dmepos-geographic-classifications



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Data on Suppliers with Specific Supplier Type Codes
Sorted by: Primary Supplier Type Code, Supplier ZIP Code (5-digit), Supplier ZIP Code (4-digit)
Suppliers with Active Med IDs Only
Primary Supplier Type Codes: 51, 52, 53, 54, 58, A6, B1, B3

Noridian Healthcare Solutions, LLC

These represent NPI numbers (locations)

ALL DMEPOS SUPPLIER CATEGORIES INCLUDING O&P AND PEDORTHIC

Supplier Type Code	Supplier Type Code Description	Count of Suppliers with Active Med ID	Count of Suppliers with Active Med ID	Count of Suppliers with Active Med ID	Count of Suppliers with Active Med ID	Count of Suppliers with Active Med ID	Count of Suppliers with Active Med ID	Count of Suppliers with Active Med ID	Count of Suppliers with Active Med ID (09/14/2017)	Count of Suppliers with Active Med ID (04/20/2018)	2010-2018 Decrease (%)
54	"MEDICAL SUPPLY COMPANY NOT INCLUDED IN 51, 52 OR 53"	9,443	9,507	8,888	8,230	7,837	7,483	7256	7,081	7,018	25.68%
A6	MEDICAL SUPPLY COMPANY WITH RESPIRATORY THERAPIST	2,109	1,974	1,946	1,881	1,786	1,717	1852	1,809	1,750	17.02%
53	MEDICAL SUPPLY COMPANY WITH PROSTHETIC/ORTHOTIC PERSONNEL CERTIFIED BY AN ACCREDITING ORGANIZATION	695	693	699	675	820	852	943	945	963	-38.56%
51	MEDICAL SUPPLY COMPANY WITH ORTHOTIC PERSONNEL CERTIFIED BY AN ACCREDITING ORGANIZATION	417	403	391	361	357	331	391	379	385	7.67%
52	MEDICAL SUPPLY COMPANY WITH PROSTHETIC PERSONNEL CERTIFIED BY AN ACCREDITING ORGANIZATION	310	284	267	246	237	220	281	278	271	12.58%
58	MEDICAL SUPPLY COMPANY WITH REGISTERED PHARMACIST	58	69	73	85	88	84	101	107	101	-74.14%
B3	MEDICAL SUPPLY COMPANY WITH PEDORTHIC PERSONNEL	63	76	101	115	106	101	113	109	111	-76.19%
B1	OXYGEN & EQUIPMENT	67	82	97	94	95	91	94	94	97	-44.78%
		13,162	13,088	12,462	11,687	11,326	10,879	11,031	10,802	10,696	18.74%

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SUPPLIER CATEGORIES EXCLUDING O&P AND PEDORTHIC

Supplier Type Code	Supplier Type Code Description	Count of Suppliers with Active Med ID	Count of Suppliers with Active Med ID	Count of Suppliers with Active Med ID	Count of Suppliers with Active Med ID	Count of Suppliers with Active Med ID	Count of Suppliers with Active Med ID	Count of Suppliers with Active Med ID	Count of Suppliers with Active Med ID (09/14/2017)	Count of Suppliers with Active Med ID (04/20/2018)
54	"MEDICAL SUPPLY COMPANY NOT INCLUDED IN 51, 52 OR 53"	9,443	9,507	8,888	8,230	7,837	7,483	7256	7,081	7,018
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58	MEDICAL SUPPLY COMPANY WITH REGISTERED PHARMACIST	58	69	73	85	88	84	101	107	101
B1	OXYGEN & EQUIPMENT	67	82	97	94	95	91	94	94	97
		11,677	11,632	11,004	10,290	9,806	9,375	9,303	9,091	8,966

SUPPLIER CATEGORY OF PHARMACY

Supplier Type Code	Supplier Type Code Description	Suppliers with Active Med ID (11/16/2010)	Suppliers with Active Med ID (10/01/2011)	Suppliers with Active Med ID (10/01/2012)	Suppliers with Active Med ID (10/01/2013)	Suppliers with Active Med ID (10/01/2014)	Suppliers with Active Med ID (10/01/2015)	Suppliers with Active Med ID (10/01/2016)	Count of Suppliers with Active Med ID (10/01/2017)
A5	PHARMACY	49,985	50,723	49,857	49,940	50,069	49,947	50,007	49,456

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Slowing Trend

	Number of DMEPOS Locations (Rooftops) by State															
DATE	7/13	11/14	4/15	8/15	10/15	1/16	4/16	7/16	10/16	1/17	4/17	7/17	9/17	4/18	Difference Between 07/13 and 04/18	Difference Between 09/17 and 04/18
TOTAL	16,389	14,827	13,723	13,489	13,289	13,094	13,007	10,677	10,504	10,278	10,046	9,810	8,781	8,093		
TX	1,242	1,030	996	954	949	926	913	755	750	736	724	711	702	688	-44.6	-2.0

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A "Proposed Rule"

- On July 11, 2018, CMS posted online the annual End-Stage Renal Disease (ESRD) proposed rule, which includes proposals for the DMEPOS Medicare benefit
- The rule introduces changes to the DMEPOS Competitive Bidding Program (CBP), which includes:
  - Overall program changes
  - A hold on bidding until CMS assesses the program's sustainability
  - Proposed changes to the oxygen benefit, a new fee schedule methodology for multi-functioning ventilators and Norther Mariana Islands added to the mail order program
- Comments to this proposed rule are due on September 10, 2018

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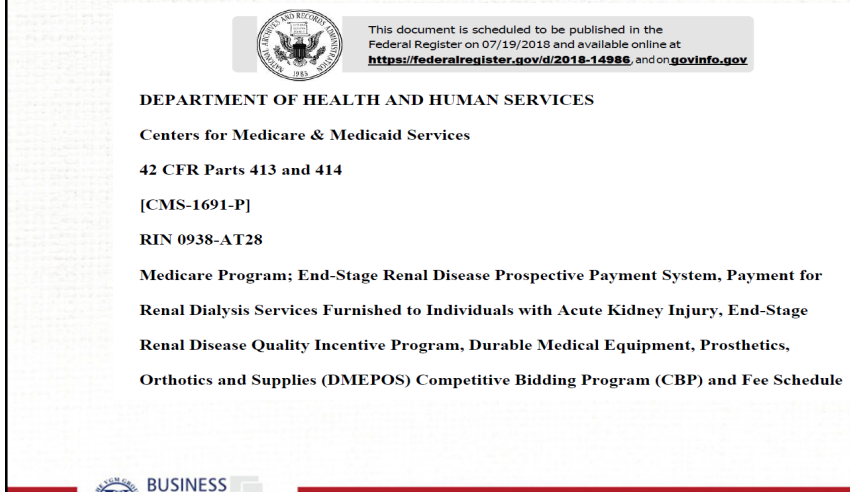
A "Proposed Rule"



This document is scheduled to be published in the Federal Register on 07/19/2018 and available online at https://federalregister.gov/d/2018-14986, and on govinfo.gov

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413 and 414

[CMS-1691-P]

RIN 0938-AT28

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 (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule

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A "Proposed Rule"

- Most notably, this Proposed Rule puts $1 billion back into the HME Industry
- The Administration recognized the shortcomings of the current program and need for reform, as well as relief for rural areas throughout the country
- CMS acknowledged the unsustainability of the current program and is soliciting comments as it moves forward

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Positive Provisions

- Coupled with the previously mentioned "interim final rule" which increased reimbursement to the rural areas from June 1 to 12/31/18, this Proposed Rule contains several positive provisions impacting the HME community, including:
  - Implement "lead item pricing" for future rounds of bidding
  - Clearing price is used when determining SPAs in future rounds (referred to as the "maximum winning bids")

Positive Provisions

- Allows any willing provider in good standing to serve Medicare beneficiaries until the next round of bidding occurs (date TBD; we believe 1/1/2021)
- Extends the relief set forth in the IFR for rural and non-contiguous areas with a 50/50 blended rate through 12/31/2020
- New Payment Classes for Oxygen and Oxygen Equipment and Methodology for Ensuring Annual Budget Neutrality of the new classes
- Payment for certain "Multi-Function Ventilators"

Lead Item Bidding

- 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

Lead Item Bidding

- Bid for the lead item will be the "composite bid" used to establish the SPAs for the lead item and all other items in the product category. The lead item will be identified based on total national allowed charges rather than total national allowed services:
  - For example, there are far more allowed services for negative pressure wound therapy (NPWT) dressings than NPWT pump rentals, but the revenue that is generated by the pump rentals is more than double the revenue generated by the dressings

Commentary

- The likelihood of larger, conglomerate product categories established to promote "one-stop shopping" for beneficiaries and referral agents would need to be split into multiple product categories so that lead item pricing is not implemented for categories that include different types of base equipment
  - Such categories should include respiratory equipment (oxygen and oxygen equipment, continuous positive airway pressure devices and respiratory assist devices)
  - Other options: general home equipment (hospital beds, support surfaces, commode chairs, patient lifts and seat lifts) and standard mobility equipment (walkers, standard manual wheelchairs, standard power wheelchairs and scooters)

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SUMMARY OF PROPOSED CHANGES TO DURABLE MEDICAL EQUIPMENT COMPETITIVE BIDDING PROGRAM

PROPOSED BY CMS ON JULY 11, 2018[1]

Issue	Proposal	Comments
Lead Item Pricing for all product categories	CMS addressed the issue of price inversion in the 2016 payment rule. The new rule applies the policy more broadly, to cover all items in the product category rather than groupings of items in a product category. In addition, the lead item would be identified based on charges, rather than total national allowed services. The new policy replaces the current bidding process (under which bids are submitted for each product category). Budget neutrality would be assured by requiring that the supplier's bid for the lead item (as re-defined) could not exceed the fee schedule amount that would otherwise apply. This change would be effective for new competitions occurring after January 1, 2019.	The change was made to address the phenomenon of "price inversion": that is, where the price of a more complicated item of DME (e.g., walker with wheels) is less expensive than a less complicated version (walker without wheels). CMS states that the new bidding policy is expected to dramatically simplify the bidding process.

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Commentary

- CMS expects expenditures for the lead item will increase, but this increase will have an off-set by decreases in expenditures for the non-lead items
- Small suppliers are awarded contracts due to CMS' requirement to meet small supplier target will not have their bids be considered in maximum winning bid
- Small suppliers who refuse a contract will not be forced to accept the contract
- CMS stated that it takes about two years to prepare and implement a new round of bidding. CMS will educate the supplier community on lead item pricing

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CMS proposes to use the maximum winning bid to establish the SPAs

Calculation of single payment amounts (SPAs) using maximum winning bids for lead items	Under the policy, the SPA for the lead item in each product category in a competitive bidding area would be based upon the maximum (or highest) bid amount by suppliers in the winning range. The SPAs for all other items in the product category would equal a percentage (ratio of the average fee schedule amount for the item to the average fee schedule	This seems to be a significant change to CMS policy and one that will be favorable to suppliers. In addition to being favorable suppliers (and thereby ensuring the sustainability of the program), CMS believes that the policy change will simplify the bidding process.

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Current Rounds Expiration

- According to CMS Media Relations: "The process for recompeting contracts with suppliers currently in effect under the DMEPOS CBP has not yet been initiated. As a result, we note that the current contracts for the DMEPOS CBP will expire on December 31, 2018."
- Accordingly, beginning January 1, 2019, and until new contracts are awarded under the DMEPOS CBP, beneficiaries may receive DMEPOS items from any Medicare enrolled DMEPOS supplier

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The "5%" Issue

- A number of DME suppliers have entered into common ownership arrangements that allow a non-CB contract supplier to be added to the CB contract of a CB contract supplier
- If such a common ownership arrangement terminates Dec 31, 2018, former commonly-owned suppliers can submit their own bids during the next round of bidding

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CBAs

- CMS is proposing a specific fee schedule adjustment methodology for items and services furnished within former CBAs
- Propose to establish a methodology for adjusting fee schedule amounts paid in areas that were formerly CBAs during periods when there is a temporary lapse in the CBP (after Dec 31, 2018)

CBAs

- CMS proposes to adjust the fee schedule amounts for items and services furnished in former CBAs based on the SPAs in effect in the CBA on the last day before the CBP contract periods of performance ended (Dec 31, 2018), increased by the projected percentage change in the CPI for all Urban Consumers (CPI–U) for the 12-month period on the date after the contract periods ended (Jan 1, 2019)

CBAs

- If the gap in the CBP lasts for more than 12 months (through the end of 2019), the fee schedule amounts are increased once every 12 months 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

Rural/Non-Contiguous Areas

- CMS is proposing to adjust the fee schedule amounts for items and services furnished in rural and non-contiguous non-CBAs by extending through Dec 31, 2020, the current methodology which bases the fee schedule amounts on a blend of 50 percent of the adjusted fee schedule amounts and 50 percent of the unadjusted fee schedule amount

(Note: To be clear, this applies ONLY to rural Zip Codes, Alaska and Hawaii, with the exception of the Honolulu CBA)

Non CBA & Non-Rural

- For items and services furnished in non-CBAs that are not rural or non-contiguous areas with dates of service from Jan 1, 2019, through Dec 31, 2020, the fee schedule amount for the area is equal to 100 percent of the adjusted payment amount

(Again, to be clear, there is no 50/50 blend)

Non CBA & Non-Rural

- CMS offers…"However, we request specific comments on the issue of whether the 50/50 blended rates should apply to these areas as well. We plan to continue monitoring health outcomes, assignment rates, and other information and would address fee schedule adjustments for all non-CBAs for items furnished on or after Jan 1, 2021, in future rulemaking."
- The rule proposes to put these new rates into effect until Dec 31, 2020. CMS is monitoring outcomes related to access before implementing the next round of bidding. CMS will address fee schedules beginning Jan 1, 2021 in a separate rule

New Payment Classes for Oxygen

- CMS will also add new payment classes for portable liquid oxygen equipment only, portable gaseous oxygen equipment only, and high flow portable liquid oxygen contents
- It also proposes "to establish a new methodology for ensuring that all new payment classes for oxygen and oxygen equipment added since 2006 are budget neutral…"

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Changes to Oxygen Payment

- Due to the low reimbursement rate of servicing portable liquid oxygen, CMS is proposing to split the portable oxygen into two separate classes (gas and liquid) and increase the portable liquid oxygen rate to the OPGE rate. CMS' goal is to decrease incentives to prescribe OPGE

TABLE 53: Current and Proposed Oxygen and Oxygen Equipment Classes

Current Oxygen and Oxygen Equipment: 5 Classes Described in 414.226	Proposed Oxygen and Oxygen Equipment: 7 Classes
Stationary oxygen equipment (including stationary concentrators) and oxygen contents (stationary and portable)	Stationary oxygen equipment (including stationary concentrators) and oxygen contents (stationary and portable)
Portable equipment only (gaseous or liquid tanks)	Portable gaseous equipment only
	Portable liquid equipment only
Oxygen generating portable equipment only	Oxygen generating portable equipment only
Stationary oxygen contents only	Stationary oxygen contents only
Portable oxygen contents only	Portable gaseous and liquid oxygen contents only except for portable liquid oxygen contents for prescribed flow rates greater than four liters per minute
	Portable liquid oxygen contents only for prescribed flow rates greater than four liters per minute

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Changes to Oxygen Payment

- CMS proposes to add a new class for "portable liquid oxygen contents only for prescribed flow rates of more than 4 liters per minute."
- The initial reimbursement amount for this item will be 50% more than the portable oxygen contents fee schedule. Moving forward, the price would be adjusted based on CBP
- Starting Jan 1, 2019, CMS proposes to apply budget neutrality offset to all oxygen contents and equipment

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Changes to Oxygen Payment

TABLE 54: January 1, 2018 Fees for Current and Proposed Budget Neutrality Methods

Current Method	2018 Rate	Proposed Method	2018 Rate
Stationary oxygen equipment (including stationary concentrators) and oxygen contents (stationary and portable)	$70.23	Stationary oxygen equipment (including stationary concentrators) and oxygen contents (stationary and portable)	$72.59
Portable equipment only (gaseous or liquid tanks)	$17.29	Portable gaseous equipment only	$16.04
		Portable liquid equipment only	$34.73
Oxygen generating portable equipment only	$37.44	Oxygen generating portable equipment only	$34.73
Stationary oxygen contents only	$53.32	Stationary oxygen contents only	$49.46
Portable oxygen contents only	$53.32	Portable gaseous and liquid oxygen contents only with the exception of portable liquid contents greater than four liters per minute	$49.46
		Portable liquid contents only greater than four liters per minute	$74.19

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Moving Forward on Non-Bid Area and Oxygen Relief

- The ESRD/DMEPOS Rule fails to provide relief for those non-CBA providers who are not located in rural or non-contiguous (i.e. Alaska & Hawaii) areas
  - CMS cited a lack of claims data that would indicate HME patients are having adverse health outcomes in these areas under the lower rates in effect since July 2016
  - Also took issue with assertions that travel and delivery costs in non-CBA areas are higher than in CBAs

Moving Forward on Non-Bid Area and Oxygen Relief

- Assert the non-rural, non-CBA "travel distances and costs for these areas are lower than the travel distances and costs for CBAs."
- While CMS is not providing relief for this non-bid cohort, they note that they will continue to monitor this area closely and ask for "specific comments on the issue of whether the 50/50 blended rates should apply to these areas as well."
- **A strong response on this issue from HME stakeholder groups and providers in these non-bid areas in the comment period is especially important**

"Multi-Functioning" Ventilator

- Multi-functioning ventilator is classified as a ventilator by the FDA, but it has four other functions: oxygen concentrator, nebulizer, suction pump and cough stimulators
- A new proposed fee schedule includes the current ventilator rate plus an additional amount of the average cost of oxygen concentrator, nebulizer, respiratory airway suction and cough stimulator
- The add-on rate is not affected based on the patient's utilization of the other features
  - Whether a patient uses just one feature or all the features, the add-on amount will stay constant

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"Multi-Functioning" Ventilator

- If the patient only qualifies under the ventilator criteria, Medicare will only cover the ventilator cost. Beneficiaries who receive a multi-function ventilator will not qualify for separate oxygen and oxygen equipment, nebulizers and related accessories, suction pumps and related accessories and cough stimulators and any related accessories
- Multi-functioning ventilator will be classified as in the frequent and substantial servicing payment category. This new payment methodology is effective Jan 1, 2019. CMS will publish further guidance in a separate rule
- Adding multi-functioning ventilator to the Medicare benefit will not impact beneficiary cost but is expected to cost Medicare $15 million

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Who is it?

- In April of last year, Ventec Life Systems received FDA 510(k) clearance from the U.S. Food and Drug Administration for its "VOCSN", the device that combines five respiratory therapies: ventilation, oxygen, cough, suction and nebulization
- The device has been available in a controlled rollout, with wider distribution set for late 2018, early 2019
- Some stakeholders say they are surprised, "with all the work that needs to be done to better define Medicare's policies for vents, that CMS would make this a priority."

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New CBAs

- CMS is requesting feedback on splitting large CBAs into smaller CBAs in order to establish a more manageable service area
  - Currently 9 large CBAs that have a range of 7,000-9,000 square miles
  - Phoenix-Mesa-Scottsdale, AZ; Boise City, ID; Dallas-Fort Worth-Arlington, TX; Riverside-San Bernardino-Ontario, CA; Houston-The Woodlands-Sugar Land, TX; Bakersfield, CA; Salt Lake City, UT; San Antonio-New Braunfels, TX; and Atlanta-Sandy Springs-Roswell, GA
- CMS acknowledges that subdividing these large CBAs would mean suppliers bidding in these areas would need to obtain more surety bonds

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Comments

- **Comments to this proposed rule ended on September 10, 2018**
- VGM, AAHomecare and numerous stakeholders representing state associations, HME suppliers and manufacturers/distributors offered substantial input via the comment process

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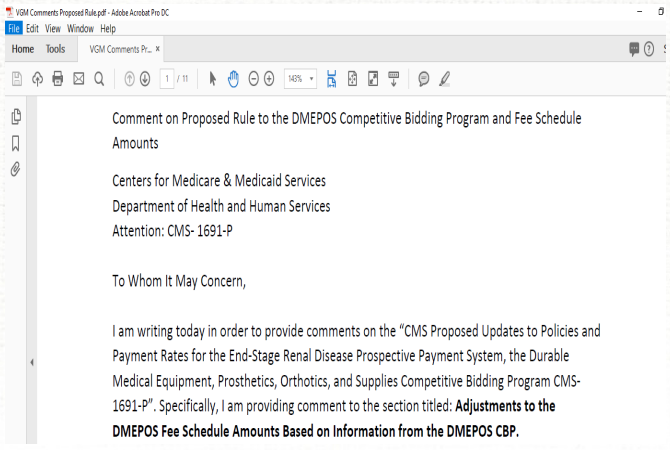
Comments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Comment on Proposed Rule to the DMEPOS Competitive Bidding Program and Fee Schedule Amounts

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS- 1691-P

To Whom It May Concern,

I am writing today in order to provide comments on the "CMS Proposed Updates to Policies and Payment Rates for the End-Stage Renal Disease Prospective Payment System, the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Competitive Bidding Program CMS-1691-P". Specifically, I am providing comment to the section titled: **Adjustments to the DMEPOS Fee Schedule Amounts Based on Information from the DMEPOS CBP.**

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Conclusion

- There are major provisions within the ESRD, which contains proposals for modifying the competitive bidding program
- While CME is calling this "modernizing" the DMEPOS program, disguising it as an overhaul, this proposed rule, as currently written, is a missed opportunity for major regulatory reform to strengthen access to DME in urban, non-rural and rural areas across the country

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Conclusion

- In reality, while the competitive bidding program is inevitably delayed until CMS conducts another round of bidding, CMS has effectively extended the current program, with no indication of when the next program will be
- The status of the industry right now is not acceptable, as suppliers are at the mercy of CMS to make these crucial changes

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New Mapping Tool Available

- VGM launched an interactive mapping tool that allows suppliers to see where reimbursement lines fall
- **http://www.vgmdclink.com/resource-center/dmepos-geographic-classifications**

Questions?

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