



FISCAL YEARS 2017-2019

# COMPETITIVE ACQUISITION OMBUDSMAN REPORT TO CONGRESS

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# A MESSAGE FROM THE OMBUDSMAN

As the Ombudsman for Medicare’s Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP), establishing and maintaining relationships with partners and advocates is a major and important aspect of my work. Over the past three years, I have made significant progress in developing an engagement framework for the identification of program issues and concerns and subsequent resolutions. This approach has had a meaningful and positive impact on DMEPOS CBP suppliers (hereafter referred to as “suppliers”) and beneficiaries using DMEPOS. New relationships with national disease-focused organizations have allowed me to provide considerable feedback to advocates and oxygen suppliers to strengthen information and instructions on how to fully utilize the DMEPOS CBP inquiry and complaint process. As the Ombudsman, I also worked with Centers for Medicare & Medicaid Services (CMS) colleagues and national and local supplier associations to support training and outreach to suppliers to address concerns about denied claims. At the same time, I relayed supplier feedback directly to CMS so the Agency could consider the impact of the DMEPOS CBP on suppliers in regulatory decisions. In 2018, while major regulatory changes were finalized, competitive bidding contracts ended, and a temporary gap period of the DMEPOS CBP was announced, I worked with partners and stakeholders to communicate how to achieve continuity of care during the impending temporary delay of the program.

From 2017 through 2019, addressing beneficiary and supplier concerns continued to be a major focus of my role, especially as the availability of DME became the theme of supplier feedback when fee schedule adjustments based on information from the DMEPOS CPB were applied to items and services furnished in non-competitive bidding areas (non-CBAs).

Further, partnerships and engagements allowed me to quickly assess the impact of Hurricanes Maria, Harvey, and Irma, as well as the California wildfires, on access to DME. Working with national associations and suppliers in the affected areas brought an important perspective to recovery efforts. CMS worked expeditiously to ensure appropriate payment mechanisms were in place to address the replacement of DME in CBAs.

Finally, as a major National Mail Order Program (NMOP) supplier left the program, leaving many beneficiaries having to transition to new suppliers, I worked closely with national diabetes organizations and suppliers to monitor any potential delays and challenges beneficiaries encountered. Efforts to monitor complaints and inquiries helped smooth the transition for affected beneficiaries when supply disruptions and changes had the potential to impact service and access.

My engagements with suppliers, providers, beneficiary advocates, and CMS components helped to identify issues and resolve them through facilitation and commitment to improving the DMEPOS CBP. I thank our partners and the many dedicated CMS subject matter experts that worked to document and respond to DMEPOS CBP complaints and inquiries, communicate DMEPOS CBP information, and report data.

I look forward to continued engagement with all stakeholders and supporting CMS as the DMEPOS CBP further evolves.



Tangita Daramola  
Competitive Acquisition  
Ombudsman

*A note about future CAO Reports to Congress: Beginning with the report covering CAO activities in 2020, CMS will aim to report based on the calendar year rather than the fiscal year (FY). This approach would align the CAO Report to Congress reporting cycle with the annual nature of many of Medicare’s DMEPOS policies.*

# ABOUT THE DMEPOS COMPETITIVE BIDDING PROGRAM

From 2017 through 2019, CMS continued the expansion of DMEPOS CBP pricing by aligning DMEPOS fee schedule amounts with DMEPOS CBP payment amounts.<sup>1</sup> Information from the DMEPOS CBP was used to adjust the DMEPOS fee schedule in non-CBAs.<sup>2</sup> The timeframe for transitioning to fully adjusted rates<sup>3</sup> was extended to provide suppliers in non-CBAs additional time to effectively handle pricing changes.<sup>4</sup> The fully adjusted amounts were in effect in non-CBAs beginning January 1, 2017. Additionally, Congress mandated that CMS solicit and take into account stakeholder input when making any adjustments to DMEPOS fee schedule amounts.<sup>5</sup>

As the Ombudsman for the DMEPOS CBP, I review and hear inquiries and complaints from suppliers and individuals regarding the DMEPOS CBP.<sup>6</sup> As the pricing from the DMEPOS CBP was used to adjust fee schedule amounts for items and services furnished in non-CBAs, I heard inquiries and complaints from stakeholders in those areas as well as from stakeholders in CBAs. Feedback from suppliers in non-CBAs focused on the impact of fee schedule adjustments that were informed by the DMEPOS CBP on service and access. Following the mandate to account for stakeholder input, CMS held a call in March of 2017, and suppliers shared considerable concerns about supplier capacity and beneficiary access. In 2018, CMS made regulatory changes<sup>7,8</sup> to increase and maintain payments in rural and non-contiguous areas not subject to competitive bidding based on the longer average travel distance for suppliers furnishing items in certain rural areas, the significantly lower average volume that most non-CBA suppliers furnish, and the decrease in the number of supplier locations in some areas.<sup>9,10</sup>

Additionally, in 2018, CMS reassessed the DMEPOS CBP and the fee schedule adjustments based on competitive bidding pricing and went through rulemaking to make significant market-oriented reforms to the DMEPOS CBP. A two-year temporary gap period<sup>11</sup> in the DMEPOS CBP began on January 1, 2019.<sup>12</sup> The Agency's regulatory actions were focused on improving the DMEPOS CBP by streamlining the program, enhancing quality and access to innovative products, and ensuring the long-term sustainability of the DMEPOS CBP and the savings it generates.<sup>13</sup>

**Figure 1. Key Changes to the DMEPOS CBP and DMEPOS Pricing**



Throughout this period, I used feedback from stakeholders together with inquiry and complaint data to identify potential issues resulting from the DMEPOS CBP, including areas impacted by fee schedule adjustments in which the application of the DMEPOS CBP informed those adjustments, and notified CMS program components about issues and concerns raised. This mechanism has helped to ensure that beneficiaries have access to high-quality DMEPOS items and services, and that the agency considers the perspectives of suppliers, providers, beneficiaries, Medicare beneficiary advocates, and other important stakeholders in creating and implementing policies.

## ENGAGEMENT HIGHLIGHTS OF THE CAO, FY17–FY19

“Meeting directly with stakeholders is a critical part of my role as CAO.” ~ Tangita Daramola, CAO

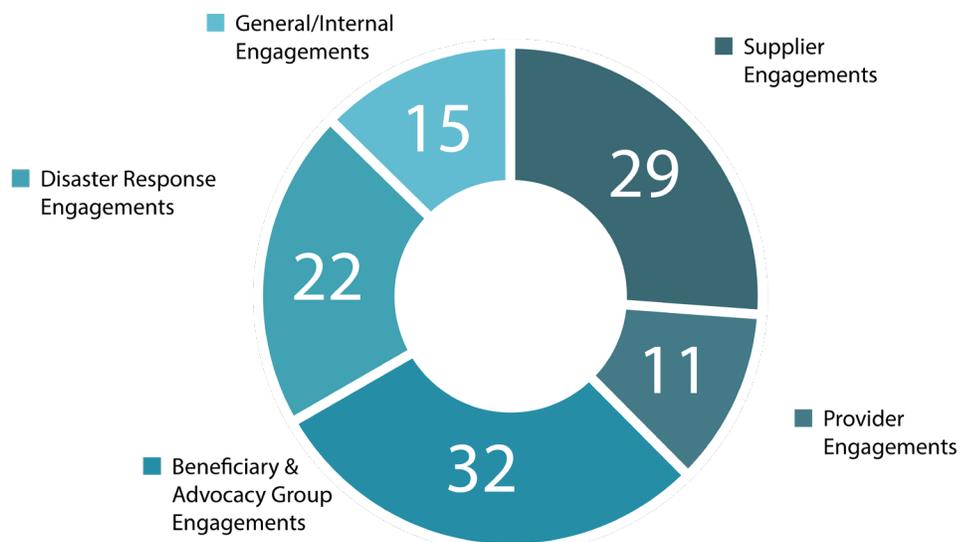
In order to gain a comprehensive understanding of the issues and complaints received from beneficiaries, suppliers, and other stakeholders, it is necessary to listen intently to potential issues and concerns raised by advocacy and supplier organizations, as well as provider groups. Because these organizations are impacted by CMS requirements, they have tremendous insight into barriers experienced by those who use the health care system. During this time, I engaged in over 100 meetings and collaborative activities with various stakeholders, including CMS components, federal agencies, state and local agencies, supplier associations, beneficiary advocacy groups, DME Medicare Administrative Contractors’ (DMAC) Medical Directors, state medical associations, and individual suppliers. All of these engagements led to greater insight into the potential issues and concerns about the DMEPOS CBP and informed my responses to complaints and inquiries about the DMEPOS CBP.

I also worked with the State Health Insurance Assistance

Programs (SHIPs), the Department of Health and Human Services (HHS) Administration on Community Living (ACL), the CMS Center for Program Integrity, the CMS regional offices, and the HHS Office of the Inspector General (OIG) to address complaints on fraud and abuse involving beneficiaries receiving unwanted DME and experiencing teleprescribing fraud.<sup>14,15</sup> Other notable engagements included on-site meetings with national supplier organizations, DMACs and Medicare Administrative

Contractors (MACs), hospital associations, provider groups, and other subject matter experts. One result of these engagements was the establishment of partnerships with a medical teaching institution to help educate providers on CMS compliance requirements relative to ordering DMEPOS. My engagements with providers, suppliers, and beneficiary advocacy organizations, as well as federal disaster management agencies, were critical to resolving issues affecting beneficiaries that use DME, including those residing in CBAs.

**Figure 2. CAO Stakeholder Engagements**



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## NOTABLE ENGAGEMENTS

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### *Reducing Burden on Providers and Suppliers*

I collaborated with the Small Business Administration's (SBA) National Ombudsman to address the complaints they received from suppliers regarding the impact of adjusted and blended fee schedule rates in non-CBAs and increased audits, which they argued greatly impacted their ability to maintain quality business practices. My partnership with the SBA National Ombudsman included an engagement with a national supplier organization representing independent medical equipment suppliers. Together, we presented on a panel of Medicare specialists on claims payment and Medical Review criteria. We provided suppliers with answers on how to address claims submission issues and Medicare's processes for reviewing the accuracy of claims. Additionally, I worked with the SBA to hear concerns from Region II suppliers and to share information on the DMEPOS CBP and provider compliance topics. This engagement underscored the importance of continued supplier engagement for the purpose of obtaining our stakeholders' business perspectives and informing agency activities. Provider compliance continued to be a significant concern to some suppliers included in the DMEPOS CBP as they filed more claims and were subject to more reviews. CMS made several changes to the audit program to better help suppliers quickly improve by identifying errors and helping correct them.

- In 2017, CMS began its Targeted Probe and Educate (TPE) Program designed to help providers and suppliers reduce claim denials and appeals through one-on-one help. Over 4,800 DME providers and suppliers have been included in the TPE process since October 2017. During the review period, several large suppliers informed CMS that they were experiencing multiple audits, which were burdensome due to the large volume of additional documentation requests. In response, CMS implemented the 10-claim preview pilot for DMEPOS. This results in suppliers with no errors identified in their first 10 claims of TPE Round 1 to be released from review prior to the full 20-40 claims being requested and reviewed. On a case-by-case basis, CMS also instructed MACs to stagger reviews for providers/suppliers subjected to numerous overlapping audits. CMS continues to implement various initiatives to reduce the burden of audits.

### *Ensuring Beneficiary Access*

Throughout 2017 and 2018, I also worked closely with a major disease-focused organization's workgroup formed to address the increased frequency of patient and provider reports they had received about home oxygen problems in the United States. Whether a concern was about Medicare generally or the DMEPOS CBP, the workgroup sought to address issues including certain beneficiaries' access to home oxygen therapy, problems with equipment, and the need for increased provider and supplier education as to how to deliver home oxygen correctly and efficiently in compliance with Medicare DMEPOS supplier and quality standards.<sup>16,17</sup> To help put this in perspective, CMS did not identify any systemic issues regarding access to home oxygen in 2019.

My specific role was to ensure that providers knew and understood the inquiry and complaint process and fully utilized the Competitive Bidding Implementation Contractor (CBIC) for any complaint against contract suppliers not following DMEPOS CBP policies. I highlighted CMS guidelines for oxygen eligibility and the required documentation and participated in discussions about the experience of suppliers and adherence to those guidelines. The workgroup raised complaints about challenges gaining access to liquid oxygen for patients with disabilities, reporting that suppliers were no longer willing to provide the product because of reduced reimbursement. I worked to clarify that contract suppliers are required to provide the prescribed products and how to file complaints about suppliers that are not in compliance with DMEPOS CBP contract requirements.

It is clear that using our existing complaint process is an important tool for CMS when the providers do not believe they can get the products needed for their patients. For example, reporting complaints through the CBIC helped CMS become aware of potential contract violations. Stakeholders agreed that using the existing mechanism, which included reporting to the CBIC and contacting 1-800-MEDICARE, to provide feedback to CMS

was key to resolving these problems. The disease-focused organization published a report in the Annals of the American Thoracic Society, providing a recommendation that more “analysis is needed to quantify the unintended impact” of the DMEPOS CBP on “patients receiving supplemental oxygen from DME providers.”<sup>18</sup>

### **Hurricane Recovery**

The 2017 Atlantic hurricane season was active, deadly, and extremely destructive. As a result of several unprecedented natural disasters in Texas, Florida, Puerto Rico, and the Virgin Islands, access to DME for beneficiaries was further challenged. I conducted critical feedback sessions immediately following Hurricanes Harvey, Irma, and Maria to gain awareness of the needs of suppliers. I met with contacts from the Federal Emergency Management Agency (FEMA), health care equipment manufacturers, and supplier advocacy organizations to discuss disaster response and Medicare replacement of DME in affected areas, particularly in the Virgin Islands and Puerto Rico. I heard complaints from the Home Medical Equipment (HME) industry about challenges in providing critically needed supplies prior to declarations on the nature of the disaster. The normal requirement to conduct a face-to-face evaluation always presents challenges in disaster situations since doctors’ orders are not always readily available, and patients may have been relocated and require supplies in different jurisdictions. Some suppliers issued complaints about the lack of reimbursement for making oxygen accessible prior to an emergency and difficulties delivering supplies to patients during the disaster because the suppliers were not designated as “emergency personnel.”

- After each emergency incident, I convened meetings with suppliers in the affected areas and with DMACs and other CMS subject matter experts to communicate information on 1135 Waivers and flexibilities and mechanisms for billing during an emergency and replacements of DME. I also coordinated inquiries and complaints pertaining to DME needs in affected areas. As a result, I was able to forge relationships with FEMA and the Office of the Assistant Secretary for Preparedness and Response (ASPR) to develop content on replacement of DME after a disaster, which will help me better serve as the CAO in coming years. Further, I was able to work with disability groups to facilitate access to DME after disasters, including working with organizations representing U.S. Territories.

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## **FINDING SOLUTIONS FOR CONCERNS**

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“Making changes to a program that impacts our most vulnerable citizens continues to require close scrutiny and observance.” ~ Tangita Daramola, CAO

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My review and assessment of inquiries and complaints related to the DMEPOS CBP acknowledge the critical and necessary requirement for CMS to develop mechanisms to control costs, support appropriate utilization, and reduce fraud and abuse while balancing access to quality DME products. While a decrease in the number of suppliers in some areas has been reported,<sup>19</sup> implementation of the DMEPOS CBP has met many of its objectives, such as reducing both costs and unnecessary utilization

and preserving health outcomes. With that understanding, making changes to a program impacting our most vulnerable citizens continues to require close scrutiny and observation. In most cases, Medicare beneficiaries that use DMEPOS are vulnerable because they have greater health risks, and their health relies on the use of products and services to maintain health and wellbeing. A few notable issues that arose between 2017 and 2019, as well as the actions CMS took to address

these concerns, are summarized below. Some of the issues highlighted below are not a result of competitive bidding; however, beneficiaries and suppliers in CBAs identified these concerns as impacting their ability to obtain or provide services.

- **Transition challenges during and after implementation of Round 2 Recompete:** Because not all suppliers won contracts and others were no longer grandfathered, some beneficiaries needed to change suppliers. 1-800-MEDICARE and the broader consumer assistance program helped beneficiaries find new contracted suppliers or educated suppliers and providers on DMEPOS CBP requirements.

- **Supplier reimbursement concerns:** Suppliers in CBAs and non-CBAs provided feedback on single payment amounts and adjusted and blended DME reimbursement rates. In addition to regulatory changes, CMS provided individualized case assistance and utilized the CBIC to work with suppliers to ensure that they adhered to contract requirements. CMS also engaged in rulemaking to increase fee schedule amounts in rural and noncontiguous areas and to reassess and improve the DMEPOS CBP.<sup>20</sup>
- **Provider concerns on the complexity of ordering products:** Stakeholders continued to provide feedback on Medicare provider compliance requirements. CMS expanded the list of DME items subject to prior authorization requirements<sup>21</sup> and streamlined the audit process through TPE.
- **Removal of a major supplier of diabetes mail order supplies:** When a mail-order supplier was removed from the DMEPOS CBP, the CAO and CMS worked to transition beneficiaries to a new supplier and respond to supplier questions.
- **Delays in access at hospital discharge:** The CAO heard complaints from hospitals and health systems about challenges they faced in ensuring safe, timely discharge to post-acute care settings. The CAO together with CMS conducted listening sessions with hospital systems to get feedback and further understand their challenges accessing DME at discharge.

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## COMPETITIVE BIDDING INQUIRIES AND COMPLAINTS, FY17–FY18

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In the following two sections, I have compiled data on inquiries and complaints related to the DMEPOS CBP and relevant DME. The first section includes data from FY17 and FY18, during which the DMEPOS CBP was in effect. The second section includes data from FY19, during which the DMEPOS CBP was in a temporary gap period. Analyzing the volume of inquiries during the period when competitive bidding was in effect as well as during the temporary gap period provides a mechanism for monitoring relevant issues that impact suppliers and beneficiaries' use of DME. Continued analysis will help establish a baseline and facilitate our ability to identify and assess successes and issues related to the DMEPOS CBP and relevant DME products when the DMEPOS CBP resumes.

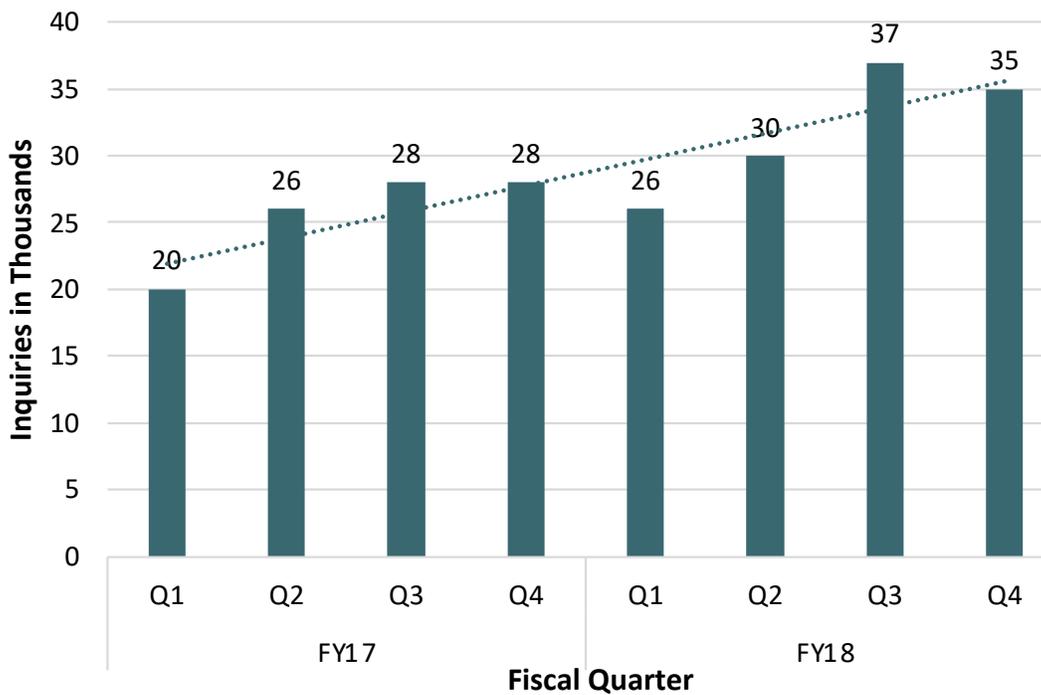
During FY17 and FY18, 1-800-MEDICARE received a total of 230,474 inquiries regarding DMEPOS from beneficiaries in CBAs.<sup>22</sup> The number of DMEPOS CBP inquiries increased by 27% from FY17 to FY18. Aside from inquiries about "general diabetes coverage,"<sup>23</sup> which accounted for nearly 30% of total inquiries during this time period, the majority of inquiries were related to wheelchairs. Other product categories that received a high number of inquiries included Continuous Positive Airway Pressure Devices and Respiratory Assist Devices (CPAP/RADs), oxygen equipment and supplies, and hospital beds.

Between FY17 and FY18, a total of 984 DMEPOS-focused complaints from beneficiaries in CBAs were escalated to the CBIC.<sup>24</sup> While 90% of complaints were escalated from 1-800-MEDICARE, the CAO and CBIC also received complaints directly from beneficiaries and their caregivers. Regardless of the source of the complaint, the CBIC investigates the details of a complaint and provides targeted supplier education, if necessary, to resolve the issue.

Overall, there were fewer complaints escalated by 1-800-MEDICARE in FY18 than in FY17. The top three complaints related to CPAP/RADs, oxygen supplies and equipment, and wheelchairs and focused on how to find suppliers and how to get equipment repaired. Issues were most commonly resolved by the current supplier or by the provision of additional education about the inquiry to the beneficiary. In other instances, the issue was resolved by finding a new supplier.

# TOTAL DMEPOS CBP INQUIRIES, FY17–FY18

Figure 3. 1-800-MEDICARE DMEPOS Inquiries by Quarter, FY2017 – FY2018



During FY17–FY18:

- There were 230,474 total inquiries regarding DMEPOS.<sup>25</sup>
- The number of inquiries trended upward, increasing from 101,462 in FY17 to 129,012 in FY18.

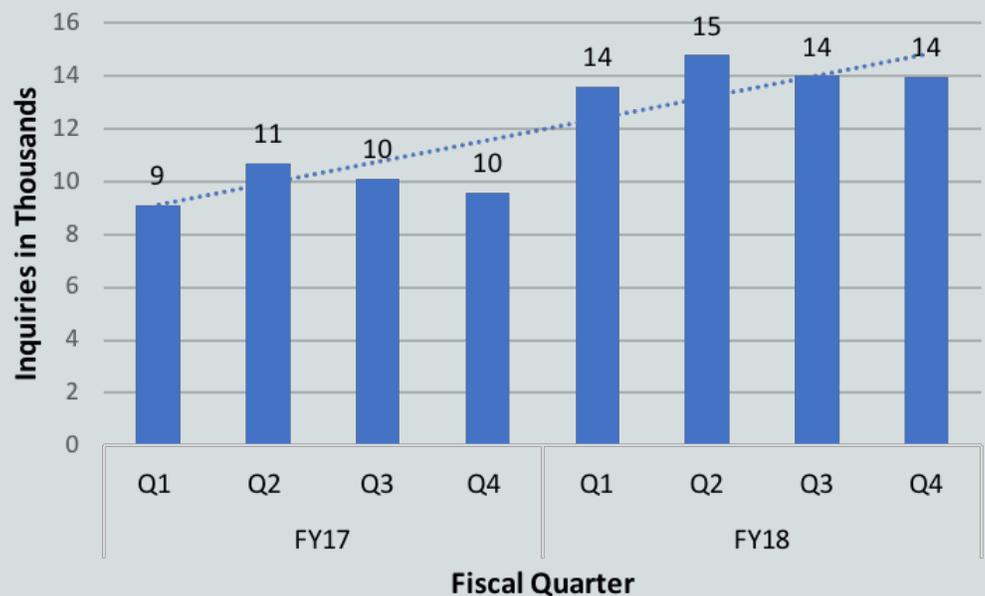
Does not include inquiries related to diabetes supplies

Source: 1-800-MEDICARE

Figure 4. Total Diabetes-Related Inquiries, FY17-FY18

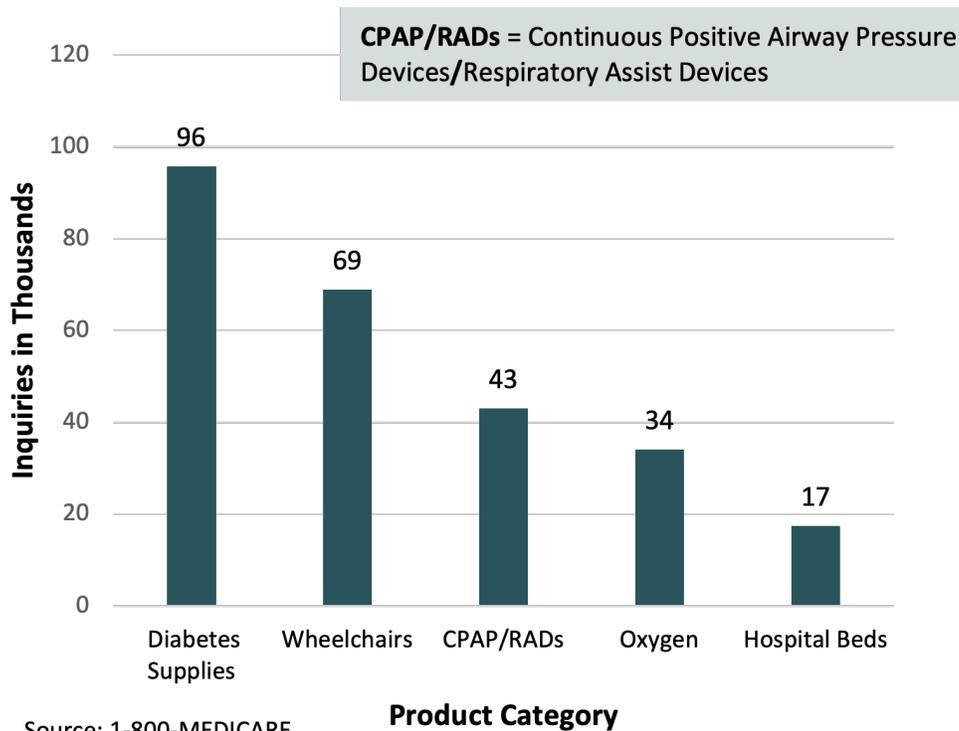
During FY17-FY18:

- Diabetes-related inquiries accounted for 29% of total inquiries.
- Diabetes-related inquiries jumped in FY18 due to a major supplier leaving the market.



Source: 1-800-MEDICARE

**Figure 5. Highest Number of DMEPOS CBP Inquiries, FY17–FY18**



During FY17–FY18:

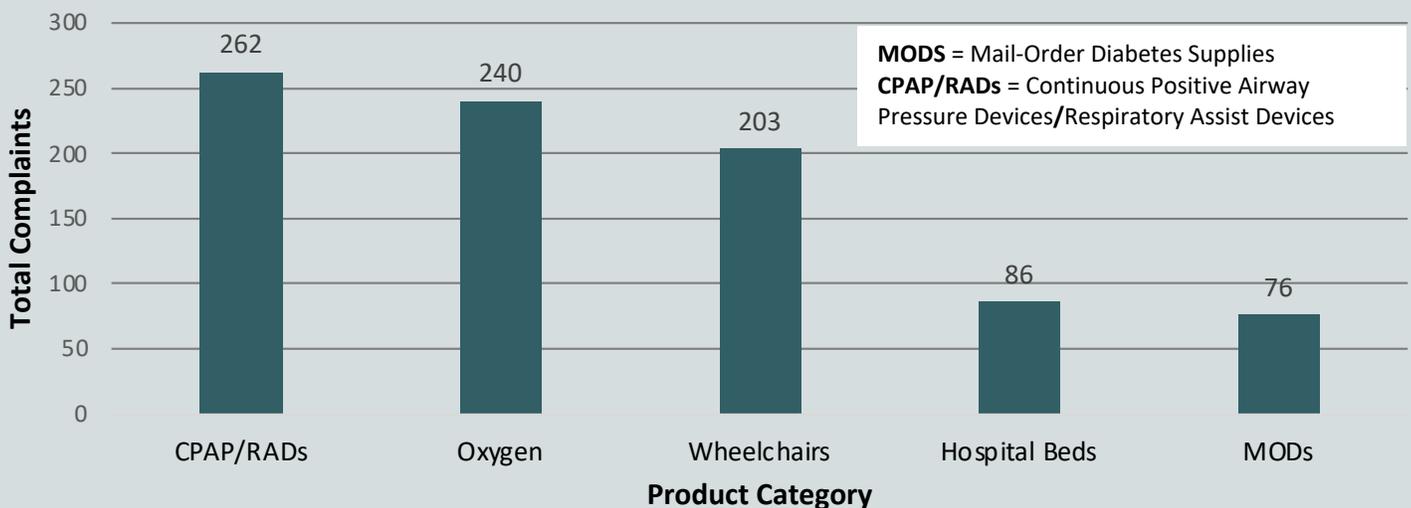
- Product categories of diabetes supplies, wheelchairs, CPAP/RADs, oxygen equipment and supplies, and hospital beds received the highest numbers of inquiries to 1-800-MEDICARE.
- Over 95,000 inquiries about diabetes general coverage alone were reported to 1-800-MEDICARE.

## TOTAL DMEPOS CBP COMPLAINTS AND RESOLUTIONS, FY17–FY18

During FY 2017 and FY 2018, when the DMEPOS CBP was in effect:

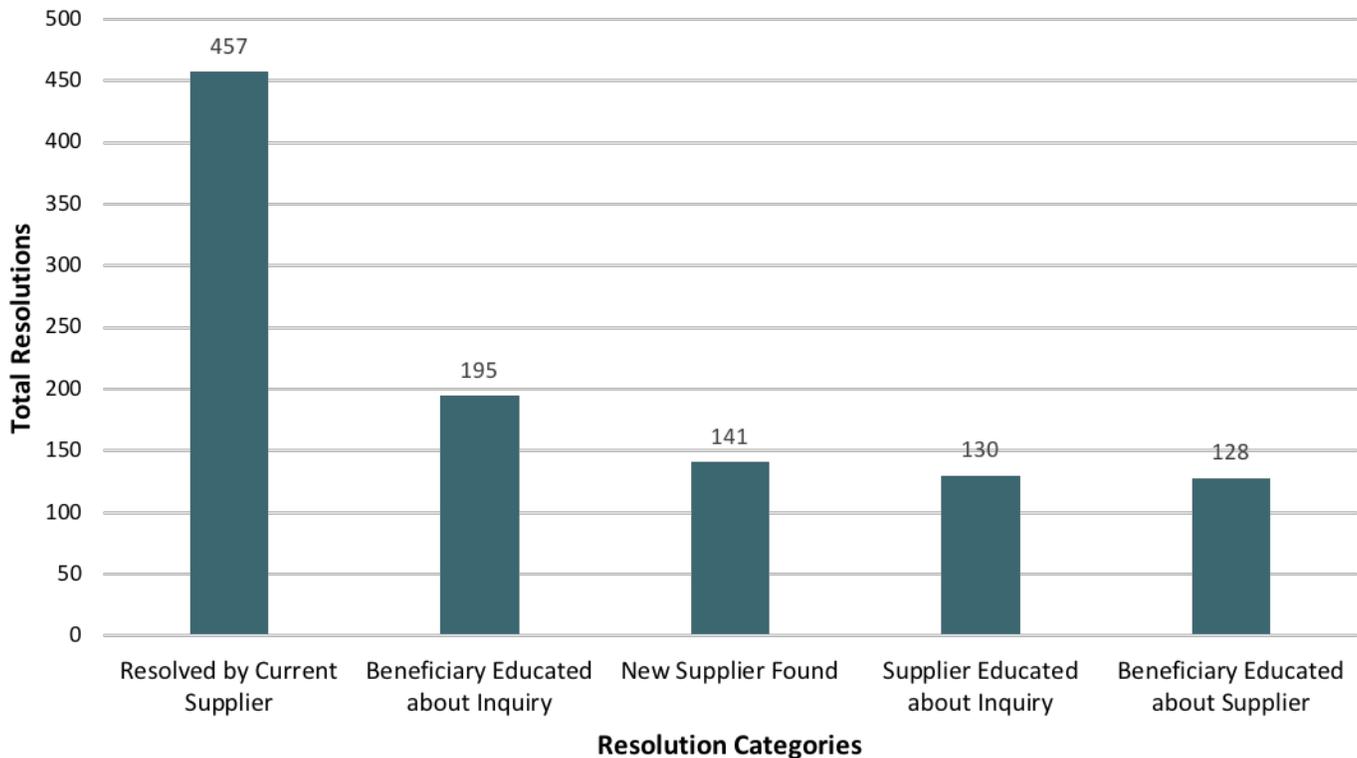
- The CAO and CBIC received a combined total of 984 complaints.<sup>26</sup>
- A total of 895 complaints were escalated to the CBIC from 1-800-MEDICARE, while 89 complaints were received directly by the CBIC and CAO.
- Total complaints decreased from 573 in FY17 to 411 in FY18, a 28% decrease over one year.

**Figure 6 – Highest Numbers of DMEPOS CBP Complaints, FY17-FY18**



- Product categories with the highest numbers of complaints were CPAP/RADs, oxygen equipment and supplies, wheelchairs, hospital beds, and mail-order diabetes supplies (MODs).
- The most common issues and corresponding product categories reported during the FY17–FY18 time period included the following:
  - Delays in access related to MODS and walkers
  - Supplier service issues related to respiratory products, MODs, and manual wheelchairs
  - Billing, coordination of benefits, or enrollment
  - Supplier compliance issues
  - Difficulties with repairs for power mobility products and hospital beds.

**Figure 7. Most Common DMEPOS CBP Complaint Resolutions, FY17-FY18**



Source: CAO-CBIC Complaint Analysis

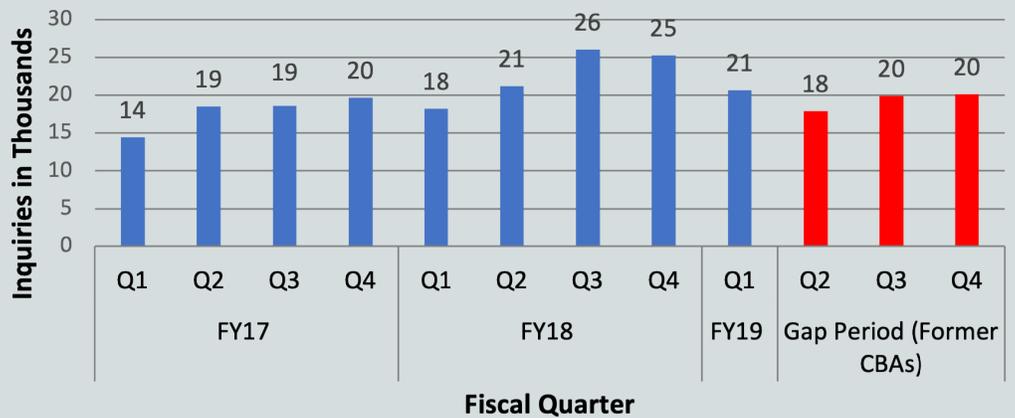
## INQUIRIES DURING THE TEMPORARY GAP PERIOD, 2019

In late 2018, CMS announced that all DMEPOS CBP contracts would end on December 31, 2018, and a temporary gap period would be in effect beginning January 1, 2019. During a gap period, any Medicare-enrolled DMEPOS supplier may furnish DMEPOS items and services to people with Medicare. This section compares the inquiries received during the DMEPOS CBP in CBAs with inquiries received during the gap period in former CBAs.<sup>27</sup> I reviewed inquiries received during the gap period and compared inquiries in the former CBAs to inquiries received in FY17 and FY18 to determine a baseline for further monitoring of inquiries and complaints.

**Figure 8. CBA and Former CBA DMEPOS Inquiries by Quarter, FY17–FY19**

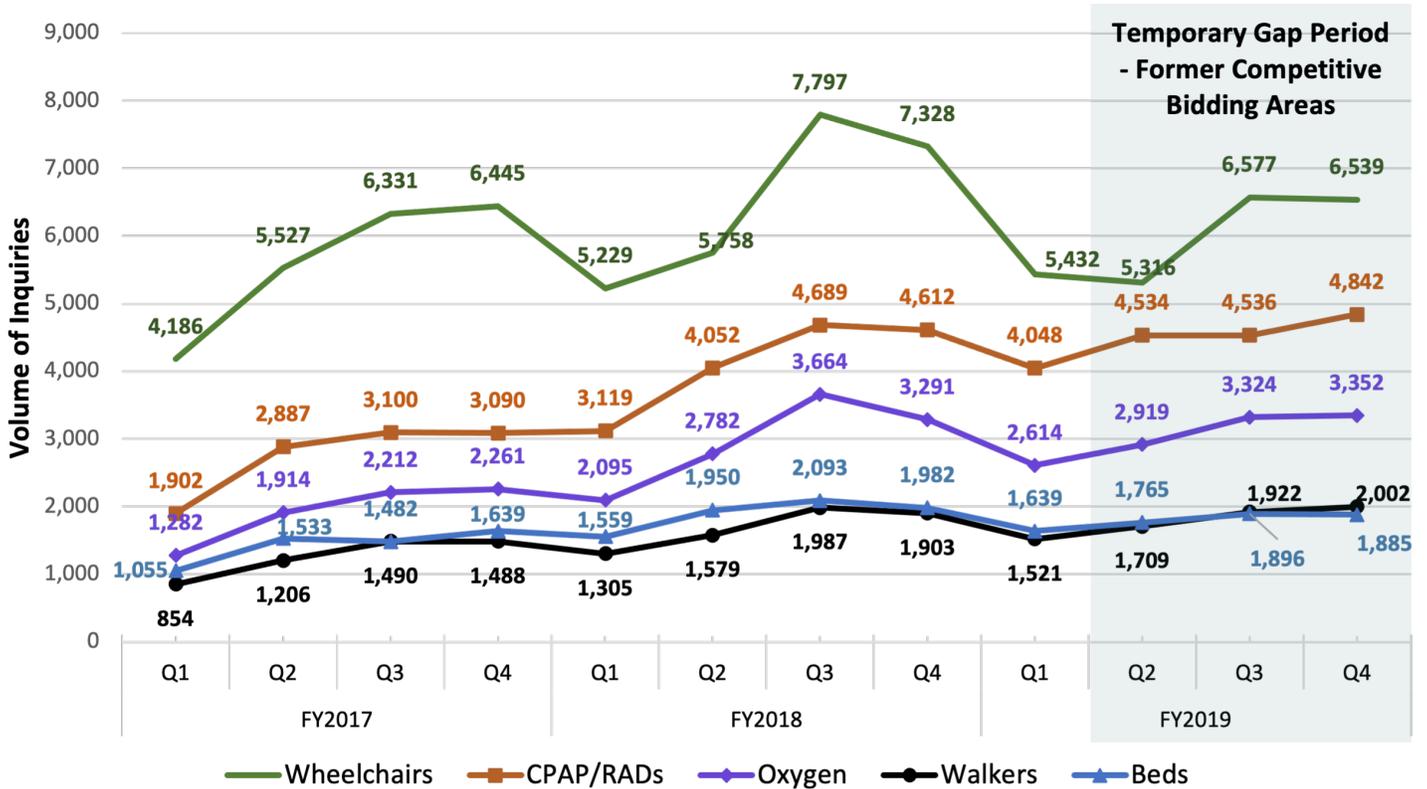
During the temporary gap period (January 1, 2019 – September 30, 2019):

- The total volume of DMEPOS inquiries decreased from FY18.<sup>28</sup>



Source: 1-800-MEDICARE

**Figure 9. Product Categories with the Highest Number of Inquiries in CBAs and Former CBAs, FY17–FY19**



Source: 1-800-MEDICARE

During the temporary gap period (January 1, 2019 – September 30, 2019):

- Overall, top product category inquiries during the gap period were lower compared to 2018. During 2019, inquiries about top product categories continued a trend upward in former CBAs, suggesting that it is important to continue monitoring to understand potential access issues within specific markets for certain product categories.<sup>29</sup>

## CONCLUSION

The DMEPOS CBP is undergoing a transformation as CMS continues to work towards increasing program efficiency and transparency, reducing provider and supplier burden, and ensuring access to DME for beneficiaries. My engagements in the field have enabled me to build partnerships and relationships with instrumental stakeholders to understand DME-related concerns and issues affecting providers, suppliers, and beneficiaries. In 2019, CMS requested additional feedback from stakeholders to further strengthen the monitoring, outreach, and enforcement functions of the DMEPOS CBP.<sup>30</sup> I plan to continue to focus on strengthening program monitoring to prepare for future rounds of the DMEPOS CBP. I look forward to continuing to engage providers, suppliers, and beneficiary advocacy organizations by listening and helping to resolve issues that impact stakeholders and beneficiaries.

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# CMS NONDISCRIMINATION NOTICE AND COMMUNICATION ACCESSIBILITY PROVISIONS FOR INDIVIDUALS WITH DISABILITIES

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## *Non-Discrimination Notice*

The Centers for Medicare & Medicaid Services (CMS) doesn't exclude, deny benefits to, or otherwise discriminate against any person on the basis of race, color, national origin, disability, sex, or age in admission to, participation in, or receipt of the services and benefits under any of its programs and activities, whether carried out by CMS directly or through a contractor or any other entity with which CMS arranges to carry out its programs and activities.

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CMS provides free auxiliary aids and services including information in accessible formats like Braille, large print, data/audio files, relay services, and TTY communications.

To request Medicare or Marketplace information in an accessible format you can:

1. Call us:

For Medicare: 1-800-MEDICARE (1-800-633-4227). TTY: 1-877-486-2048

For the Health Insurance Marketplace®: 1-800-318-2596. TTY: 1-855-889-4325

2. Email us: [altformatrequest@cms.hhs.gov](mailto:altformatrequest@cms.hhs.gov)

3. Send us a fax: 1-844-530-3676

4. Send us a letter:

Centers for Medicare & Medicaid Services

Offices of Hearings & Inquiries

7500 Security Boulevard, Room S1-13-17

Baltimore, MD 21244-1850

Attn: Customer Accessibility Resource Staff

Your request should include your name, phone number, type of information you need (if known), and the mailing address where we should send the materials. We may contact you for additional information.

Note: If you're enrolled in a Medicare Advantage Plan or Prescription Drug Plan, contact your plan to request their information in an accessible format. For Medicaid, contact your State or local Medicaid office.

## *How to File a Complaint:*

You can contact CMS in any of the ways listed above if you have any concerns about getting information in a format that you can use.

You may also file a complaint if you think you have been subjected to discrimination in a CMS program or activity. There are three ways to file a complaint with the U.S. Department of Health and Human Services, Office for Civil Rights:

Online Complaint Portal: (the link will take you directly to: <https://www.hhs.gov/civil-rights/filing-a-complaint/complaint-process/index.html>)

By email: [OCRComplaint@hhs.gov](mailto:OCRComplaint@hhs.gov)

In writing: Send information about your complaint to:

Centralized Case Management Operations  
U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Room 509F, HHH Building  
Washington, D.C. 20201

### ***CMS Accessibility & Compliance with Section 508***

CMS is committed to making its electronic and information technologies accessible to individuals with disabilities. If you cannot access content or use features on this website due to a disability, contact our Section 508 Team at [508Feedback@cms.hhs.gov](mailto:508Feedback@cms.hhs.gov). To help us better serve you, upload the material in question and/or include the URL if possible and let us know the specific problems you are having.

### ***Additional Information:***

- [What is Section 504 & how does it relate to Section 508?](#)
- [Civil Rights for Individuals & Advocates](#)
- [Section 504 Regulation Applicable to CMS](#)

# REFERENCES

- <sup>1</sup>“Report to the House Committee on Ways and Means, House Committee on Energy and Commerce, and Senate Committee on Finance: Impact of 2016 Fee Schedule Adjustments for Durable Medical Equipment Under the Medicare Program,” Secretary of Health and Human Services (Jul. 2019)
- <sup>2</sup>Social Security Act, 42 U.S.C. 1395m § 1834(a)(1)(F)(ii). [https://www.ssa.gov/OP\\_Home/ssact/title18/1834.htm](https://www.ssa.gov/OP_Home/ssact/title18/1834.htm)
- <sup>3</sup>“Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Final Rule,” 79 Fed. Reg. 215 (Nov. 6, 2014), pp 66223-66265, <https://www.govinfo.gov/content/pkg/FR-2014-11-06/pdf/2014-26182.pdf>
- <sup>4</sup>21st Century Cures Act, H.R. 34, 114th Cong. § 16007(a) (2016), <https://www.congress.gov/114/bills/hr34/BILLS-114hr34enr.xml#toc-H4EC9E-9B311EC47898D88CF7A79455128>
- <sup>5</sup>21st Century Cures Act, H.R. 34, 114th Cong. § 16008 (2016), <https://www.congress.gov/114/bills/hr34/BILLS-114hr34enr.xml#toc-H4EC9E-9B311EC47898D88CF7A79455128>
- <sup>6</sup>Section 1847(f) of the Social Security Act, 42 U.S.C. 1395w–3, specifies that the Secretary shall provide for a competitive acquisition ombudsman in order to respond to complaints and inquiries made by suppliers and individuals relating to the application of the competitive acquisition program. Section 1834(a)(1)(F)(ii) further describes the application of competitive acquisition to indicate that the Secretary may use information on the payment determined under competitive acquisition programs to adjust the payment amount in an area that is not a competitive acquisition area.
- <sup>7</sup>“Medicare Program; Durable Medical Equipment Fee Schedule Adjustments To Resume the Transitional 50/50 Blended Rates To Provide Relief in Rural Areas and Non-Contiguous Areas,” 83 Fed. Reg. 92 (May 11, 2018) pp. 21912-21925, <https://www.govinfo.gov/content/pkg/FR-2018-05-11/pdf/2018-10084.pdf>
- <sup>8</sup>“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 Amounts, and Technical Amendments To Correct Existing Regulations Related to the CBP for Certain DMEPOS,” 83 Fed. Reg. 220 (Nov. 14, 2018) pp. 56922, <https://www.govinfo.gov/app/details/FR-2018-11-14/2018-24238>
- <sup>9</sup>“CMS safeguards patient access to certain medical equipment and services in rural and other non-contiguous communities,” CMS Newsroom, The Centers for Medicare & Medicaid Service (May 9, 2018), retrieved Feb. 21, 2020, <https://www.cms.gov/newsroom/press-releases/cms-safeguards-patient-access-certain-medical-equipment-and-services-in-rural-and-other-non>
- <sup>10</sup>“Medicare Fee-for-Service: Information on the First Year of Nationwide Reduced Payment Rates for Durable Medical Equipment,” U.S. Government Accountability Office (Jul. 2018), retrieved Feb. 20, 2019, <https://www.gao.gov/assets/700/693412.pdf>
- <sup>11</sup>“Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Competitive Bidding Program: Temporary Gap Period,” The Centers for Medicare & Medicaid Services (Oct. 2018), retrieved Feb. 5, 2020, <https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/Downloads/DMEPOS-Temporary-Gap-Period-Fact-Sheet.pdf>
- <sup>12</sup>83 Fed. Reg. 220 (Nov. 14, 2018), pp. 57017-57073. <https://www.govinfo.gov/content/pkg/FR-2018-11-14/pdf/2018-24238.pdf>
- <sup>13</sup>“CMS Finalizes Policies to Modernize and Drive Innovation in Durable Medical Equipment (DME) and End-Stage Renal Disease (ESRD) Programs,” CMS Newsroom, The Centers for Medicare & Medicaid Services (Nov. 1, 2018), <https://www.cms.gov/newsroom/press-releases/cms-finalizes-policies-modernize-and-drive-innovation-durable-medical-equipment-dme-and-end-stage>
- <sup>14</sup>“AOPA Releases Statement Regarding Delivery of Orthoses through Lead Generation Marketing,” AOPA News, American Orthotic & Prosthetic Association (Mar. 28, 2019), retrieved March 5, 2020, <https://www.aopanet.org/2019/03/statement-from-the-american-orthotic-and-prosthetic-association-regarding-delivery-of-ortho-ses-through-lead-generation-marketing/>
- <sup>15</sup>“Federal Indictments & Law Enforcement Actions in One of the Largest Health Care Fraud Schemes Involving Telemedicine and Durable Medical Equipment Marketing Executives Results in Charges Against 24 Individuals Responsible for over \$1.2 Billion in Losses,” April 11, 2019. <https://www.justice.gov/opa/pr/federal-indictments-and-law-enforcement-actions-one-largest-health-care-fraud-schemes>.
- <sup>16</sup>Centers for Medicare & Medicaid Services. “Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Quality Standards.” Centers for Medicare & Medicaid Services, Jan. 9, 2018. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Downloads/Final-DME-POS-Quality-Standards-Eff-01-09-2018.pdf>.
- <sup>17</sup>“Special payment rules for items furnished by DMEPOS suppliers and issuance of DMEPOS supplier billing privileges.” 42 C.F.R. 424.57(c) (Oct. 1, 2019), <https://www.govinfo.gov/app/details/CFR-2019-title42-vol3/CFR-2019-title42-vol3-sec424-57>
- <sup>18</sup>Jacobs, Susan et al., “Optimizing Home Oxygen Therapy: An Official American Thoracic Society Workshop Report,” Annals of the American Thoracic Society 15, no. 12 (Dec. 2018):1369–81. Retrieved Dec. 9, 2019, <https://www.atsjournals.org/doi/full/10.1513/AnnalsATS.201809-627WS#i25>
- <sup>19</sup>“Medicare Fee-for-Service Information on the First Year of Nationwide Reduced Payment Rates for Durable Medical Equipment,” U.S. Government Accountability Office (Jul. 2018), retrieved Feb. 20, 2019, <https://www.gao.gov/assets/700/693412.pdf>
- <sup>20</sup>83 Fed. Reg. 92 (May 11, 2018) pp. 21912-21925, <https://www.govinfo.gov/content/pkg/FR-2018-05-11/pdf/2018-10084.pdf>
- <sup>21</sup>“Prior authorization for items frequently subject to unnecessary utilization,” 42 C.F.R. 414.234(c)(1) (Oct. 1, 2016), <https://www.govinfo.gov/app/details/CFR-2016-title42-vol3/CFR-2016-title42-vol3-sec414-234>
- <sup>22</sup>The total number of inquiries does not include inquiries related to diabetes supplies.
- <sup>23</sup>General diabetes coverage does not refer to Medicare’s coverage criteria found in the statute. It refers to the category used for inquiries received about Medicare payment.
- <sup>24</sup>For 1-800-MEDICARE’s purposes, competitive bidding-related inquiries are defined as complaints if they cannot be resolved by the initial customer service representative who receives the call and, for that reason, are escalated for further assistance. Defined capture of complaints by source began in FY14. Additionally, complaints counted here include those addressed by the CAO and the CBIC.
- <sup>25</sup>The total number of inquiries does not include inquiries related to diabetes supplies.
- <sup>26</sup>Complaints were not escalated to the CBIC during the temporary gap period; therefore, no escalated complaints were recorded in CY19.
- <sup>27</sup>Data compares the same locations during and after competitive bidding. During competitive bidding, these locations were called CBAs, and after the contracts ended, they are called former CBAs. This comparison allows us to look at inquiries in areas that no longer use contracted suppliers.
- <sup>28</sup>Total inquiries do not include diabetes related coverage inquiries.
- <sup>29</sup>Total inquiries do not include diabetes related coverage inquiries.
- <sup>30</sup>“Public Comments on Surveys,” DMEPOS Competitive Bidding, The Centers for Medicare & Medicaid Services (Nov. 20, 2019), retrieved Dec. 10, 2019, <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Comment-Period>