



2020

**COMPETITIVE
ACQUISITION
OMBUDSMAN
REPORT TO CONGRESS**



2020 Annual Report to Congress

Tangita Daramola

Competitive Acquisition Ombudsman (CAO)

Centers for Medicare & Medicaid Services

<https://www.cms.gov/Center/Special-Topic/Ombudsman-Center>



About the Ombudsman

Tangita Daramola has held the position of CAO since October 2011. The CAO prepares an annual Report to Congress describing her activities to provide Congress with an unbiased perspective on the experiences of suppliers, beneficiaries, and other stakeholders who are affected by the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP), which is administered by CMS (“the agency”). The Ombudsman provides valuable context about how the program works for stakeholders individually and within the context of the federal program offering services to medically diverse populations throughout the country. To identify and manage stakeholder concerns, the CAO performs targeted outreach, conducts research, engages with supplier and beneficiary advocates, and facilitates agency responses to inquiries and complaints.

A MESSAGE FROM THE OMBUDSMAN

I am pleased to present the CAO's Annual Report to Congress required by section 1847(f) of the Social Security Act. "Fearlessly Facing New Challenges" is an appropriate theme for the 2020 reporting period, which proved to be a challenging year as we all faced personal and professional tests for survival and determinedly sought to help those at greatest risk, persevere. Beneficiaries that use DME often face challenges that require additional efforts to support equity and the rights of beneficiaries to fair access and service. My role as CAO seeks to highlight equity concerns for these populations and support resolution of complex issues in access. This report highlights my activities as CAO related to the DMEPOS CBP, which continued in a temporary gap period throughout 2020. During this second year of the temporary gap period, I remained active in ensuring continuity of the ombudsman program by continuing to stay connected to issues encountered by beneficiaries as they obtained durable medical equipment (DME) in former competitive bidding areas (CBAs) and non-CBAs. I also strengthened many relationships in the supplier and provider communities to help ensure that valuable feedback from the field keeps the agency aware of potential areas of risk to Medicare beneficiaries.

During this reporting period, I developed a more comprehensive reporting framework for tracking and monitoring inquiries and other feedback. This updated approach, which incorporates Medicare claims data, allowed us to (1) identify markets that have higher volumes of inquiries relative to the number of DME users, and (2) track significant changes over time within a single market. This approach helped establish a baseline volume of inquiries during the temporary gap period to quickly identify any changes in inquiry volume when the DMEPOS CBP resumed at the start of 2021. Building on these improvements is crucial to obtaining relevant market-level information pertaining to access to critical life sustaining DME. In addition to advancing the analysis and reporting capabilities, I also continued to work with industry partners and CMS Regional Offices to develop stronger linkages for ongoing surveillance activities. Additionally, I continued to look deeper at persistent and ongoing issues and concerns raised over the past several years by conducting studies to review claims submissions regarding the replacement of DME for survivors after disasters.

The year 2020 proved to be extremely challenging as the nation faced the biggest health emergency in over 100 years. The COVID-19 global pandemic created new challenges for suppliers to provide necessary equipment in an environment with limitations on personal protective equipment (PPE), space in hospitals, and the ability of suppliers to safely deliver services. CMS announced many flexibilities such as conducting appointments via telehealth, relaxing face-to-face requirements, and providing PPE to help Medicare beneficiaries obtain necessary healthcare.¹

During 2020, CMS announced the future direction of the DMEPOS CBP and published the results of the bidding process that started in 2019. After initially planning to include 16 product categories as part of Round 2021, CMS removed non-invasive ventilators due to the COVID-19 pandemic in April 2020. Then, after competitively bidding 15 product categories, CMS awarded contracts to suppliers for just two products that were new to competitive bidding.

As millions of Medicare beneficiaries rely on DME each day and Medicare continues to evolve its payment policies and pricing mechanisms for DME, I am committed to further understanding the impact of these policies on beneficiaries and other stakeholders. I will continue to engage with the agency, beneficiaries, and stakeholders to create solutions as we face future challenges.

Tangita Daramola

Competitive Acquisition Ombudsman

Reflecting on Regulatory Updates

As noted in the fiscal year 2017-19 CAO Report to Congress,² since 2016, payment for DME across the country has been subject to a number of payment changes influenced by DMEPOS CBP pricing decisions, and more recently, the impact of the public health emergency (PHE). During this reporting period, these changes focused on three major topics: product categories included in DMEPOS CBP,^{3,4,5} flexibilities granted in response to the PHE,^{6,7} and the methodology for adjusting fee schedule amounts in non-CBAs.^{8,9,10} See Figure 1 for additional details.

Product Categories in the DMEPOS CBP |

Throughout the reporting period, and especially after the onset of the PHE, suppliers continually requested and supported delays in the implementation of Round 2021 due to strained supply chains, increased costs, and other operational obstacles. CMS did not make any changes to the date for the final implementation of Round 2021 but did make changes to the overall number of product categories. On October 27, 2020, CMS announced the final decision to only include the two newest product categories in Round 2021: off-the-shelf (OTS) back braces and OTS knee braces. CMS did not award contracts for the 13 product categories previously subject to competitive bidding because the bidding process did not yield payment amounts necessary to achieve expected savings.¹¹

Flexibilities in Response to the PHE - the Coronavirus Aid, Relief, and Economic Security (CARES) Act |

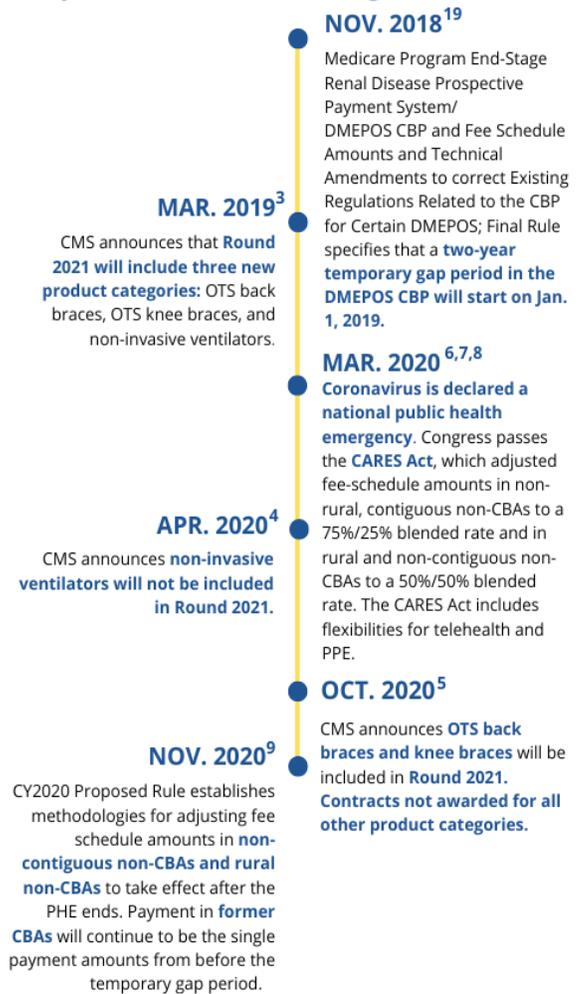
The CARES Act, enacted in March 2020, included a number of provisions that enabled flexibilities for Medicare providers and suppliers during the PHE for the COVID-19 pandemic. These included adjustments to the fee-schedule amounts for certain DME in non-CBAs and flexibilities for furnishing Medicare telehealth services.^{12,13} Additionally, CMS used emergency waiver authorities and various regulatory authorities to enable flexibilities such as waiving DME replacement requirements, some DME supplier standards, and signature and proof of delivery requirements, pausing certain prior authorization requirements, and enhancing access to telehealth.¹⁴

Fee-Schedule Adjustments in Non-CBAs | Suppliers continued to have concerns about payment rates for DME in former CBAs and non-CBAs that were determined by previous rounds of competitive bidding. On October 27, 2020, CMS issued proposed rules incorporating stakeholder feedback and concerns, to address payment rates. CMS previously established

Figure 1: Overview of Regulatory Changes

DMEPOS COMPETITIVE BIDDING PROGRAM

Key Events in Understanding 2020



transition rules for phasing in the fee schedule adjustments under 42 CFR 414.210(g)(9), and these rules addressed the phase in of the fee schedule adjustments for items furnished through December 31, 2020.¹⁵ The purpose of this proposal was to establish revised DMEPOS fee schedule adjustment methodologies for items and services furnished in non-CBAs on or after April 1, 2021, or the date immediately following the duration of the PHE for COVID-19, whichever is later. The payment adjustments resulted in increased payment for DME in non-CBAs.^{16,17} Payment in former CBAs continued to be based on single payment amounts on the last day before the CBP contract period of performance ended along with yearly consumer price adjustments from before the temporary gap period.^{18,19}

Investing in Case Management and Enhancing Data Reporting Capabilities

Responding to inquiries and complaints within the broad and diverse Medicare customer service environment requires the ability to understand the capabilities of addressing issues and concerns of more than 10 entities designed to respond to beneficiary issues. During the temporary gap period, we looked for ways to strengthen the response process for beneficiaries who use DME to ensure that these at-risk beneficiaries receive resolution of complaints quickly. We found that some complaints on quality could benefit from the Beneficiary Family Centered Care-Quality Improvement Organization (BFCC-QIO) Immediate Advocacy (IA)²⁰ process which works to mediate challenges encountered in complex situations. Beneficiaries who submit complaints about the quality of products, receiving untimely services, or receiving services in quantities that differ from the amount the provider ordered can work with mediators to intervene to achieve optimal outcomes. Work with CMS policy components and the QIO IA staff and contractors included collaborating on how to assist beneficiaries using the IA process for some DME issues. CAO research of complaints received in 2018 revealed that at least 500 referrals could have possibly taken advantage of these services. Improving triage and coordination of beneficiary cases has the potential to improve case management and outcomes of complex cases in DME access and quality concerns like intervening for resources and/or services covered by Medicare, such as a wheelchair that was not delivered.

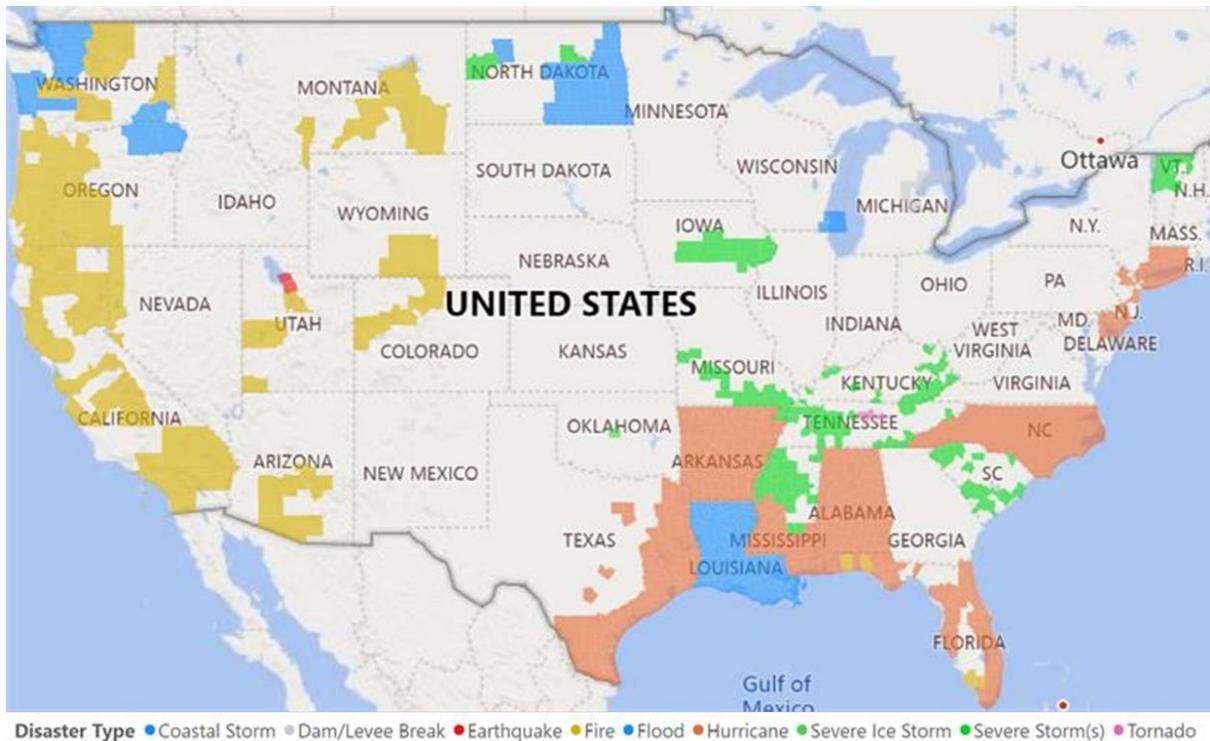
Additionally, since the beginning of the DMEPOS CBP, it has been critical to analyze data and report it in a way that provides insight into issues and concerns of at-risk beneficiaries in need of life-preserving DME. The data contained in this report is regarding inquiries about product categories that were previously included in the DMEPOS CBP. Continued monitoring of inquiries received in former CBAs provides useful information on the impact of the DMEPOS CBP given that the payment for these products continued to use the pricing mechanisms established in prior rounds of the DMEPOS CBP. A summary of inquiry data regarding product categories previously included in the DMEPOS CBP is included in the [Appendix](#).

In 2020, we made significant enhancements to the processes used to analyze inquiry data, including analyzing DME inquiries received from beneficiaries in areas that had high levels of COVID-19 cases, as well as examining the volume of inquiries relative to DME utilization in a given market. We aim to further expand our analysis to review utilization of DME and focus on changes in utilization in specific markets or for product categories with a high volume of inquiries. Additionally, reporting on inquiries received in former CBAs and non-CBAs allowed for a comparison of questions and concerns identified in areas of the country subject to different pricing methodologies.

Preparing for Disasters and Replacing DME after Disasters

Natural disasters continued to be a major focus of efforts during the 2020 reporting period. For example, there were 10 Atlantic hurricanes—including Isaias, Laura, and Sally—that were nationally declared disasters that impacted major areas of the country. Other disasters included wildfires, floods, and storms. About 15 million fee-for-service (FFS) Medicare beneficiaries reside in the disaster-affected counties (Figure 2), of which about 4 million beneficiaries use some type of DME²¹ representing about 25 to 28% of the FFS population in these areas.

Figure 2: Counties with Federally Declared Disasters in 2020²²



Recognizing that disasters affect some of Medicare’s most vulnerable beneficiaries, providing information for responders who assist beneficiaries in these areas is critical to ensuring that beneficiaries are able to obtain DME or medications that are lost or damaged. CMS policies ensure that if Medicare paid for DME, it can be replaced after a disaster.²³ We worked with HHS’s Office of the Assistant Secretary for Preparedness and Response, the Federal Emergency Management Agency (FEMA), the Administration for Children and Families, the Florida Alliance of Home Care Services, and CMS Regional Offices to develop information to train direct responders on Medicare policies and the correct approaches to reconnect survivors with appropriate resources to support replacement of their lost, damaged, or destroyed DME or medications. Additionally, we conducted research to review the replacement rates in past disasters including Hurricanes Harvey, Maria, and Michael. Findings indicated that there is a need for ongoing and continued education for beneficiaries, caregivers, and suppliers about how to replace DME and prescription drugs lost or damaged during disasters.

Strengthening Relationships between CMS and DME State Supplier Associations

CMS made significant efforts to improve meeting the needs of local providers by making changes in its regional structure to monitor and engage with local entities. CMS restructured Regional Offices to establish the Office of Program Operations & Local Engagement (OPOLE) with a goal of serving as the senior-level point of contact within each region for counterparts within CMS, HHS leadership, and external stakeholders. OPOLE creates and maintains regional location cohesion and leads regional efforts to improve stakeholder engagement.²⁴ We were able to work with national associations representing DME suppliers and manufacturers and CMS OPOLE leadership to establish greater engagement connections with 26 state associations (some associations cover multiple states). CMS continues to work closely with national and state associations and develop connections at local levels in order to ensure that topics of access and supplier feedback can be easily communicated to CMS leadership. The strengthening of these relationships promotes more engaged participation from CMS partners in agency activities. As a result of these efforts, state associations have reached out to begin inviting CMS to participate in regional and local meetings with DME suppliers. It is the hope that this will lead to enhanced meaningful engagement in CMS policies.

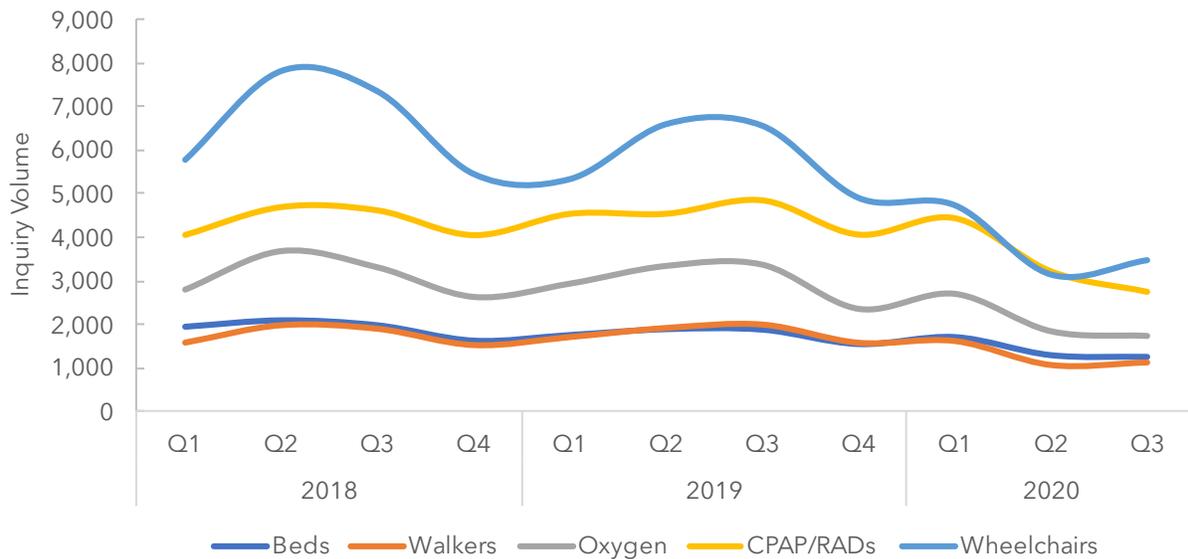
Conclusion

During the reporting period, suppliers continued to provide DME throughout the country to Medicare beneficiaries without disruptions, despite challenges facing the home medical equipment industry. The year 2020 brought with it the anticipation of specific improvements to the DMEPOS CBP to meet customer and stakeholder demands only to introduce two new product categories to competitive bidding, and not the full number of product categories bid in 2019. The PHE also had an impact on cost of care and utilization of DME as suppliers made attempts to provide services despite delays in access to important equipment and lack of PPE. In the future, the agency seeks to improve upon the savings achieved through the implementation of the DMEPOS CBP while also prioritizing adequate payment for suppliers and preserving access to DME for beneficiaries. We will continue to respond to and assist beneficiaries and individuals with inquiries and complaints. We will also monitor trends in DME utilization and access across different markets. Finally, we will continue to work with suppliers and individuals to hear feedback regarding their experience accessing DME in order to reliably and validly interpret those voices for future reporting purposes.

Appendix: Inquiries Regarding Product Categories Previously Included in the DMEPOS CBP

This section summarizes trends in inquiry volumes for select product categories previously included in the DMEPOS CBP.²⁵ The product categories displayed received the highest volume of inquiries on average when the DMEPOS CBP was in effect, as well as during the temporary gap period. In addition to trends in the volume of inquiries, this section also depicts trends in inquiry volume during the PHE. There were no complaints received during 2020 related to the DMEPOS CBP because of the temporary gap period.

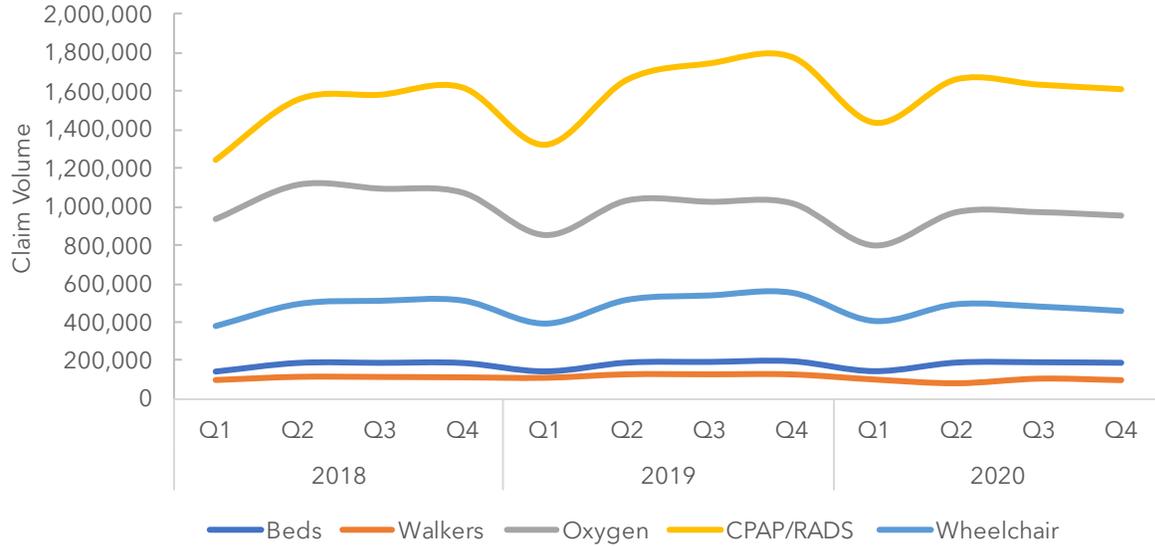
Figure 3: Inquiry Volume in CBAs and Former CBAs, 2018 - 2020



Data from Q4 2020 unavailable.
Source: 1-800-MEDICARE

Figure 3 shows that inquiries continued to decrease throughout the temporary gap period in former CBAs relative to inquiry volumes in 2018 when the DMEPOS CBP was in effect. This trend is less apparent in non-CBAs (Figure 5). The volume of inquiries in former CBAs decreased while utilization remained consistent (Figure 4).

Figure 4: Utilization in CBAs and Former CBAs, 2018 - 2020

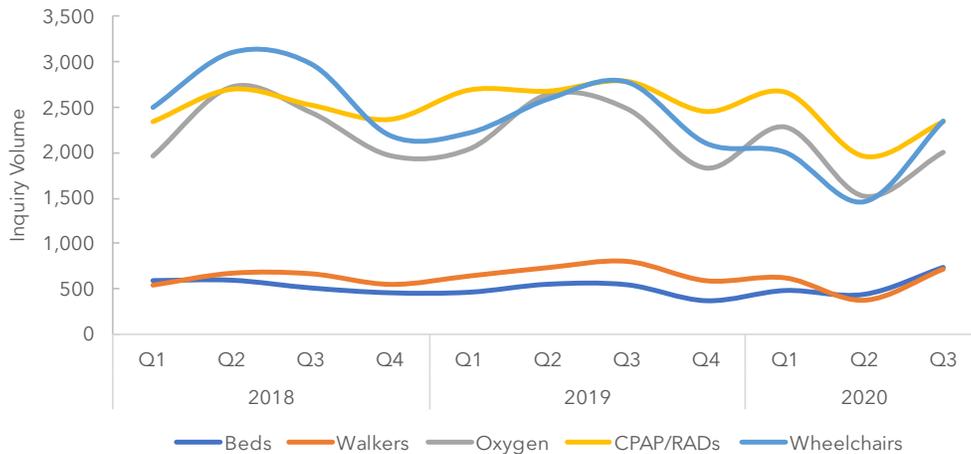


Number of unique fee-for-service paid claims for items included in the DMEPOS CBP.

Source: Integrated Data Repository

Figure 5 depicts the volume of inquiries in non-CBAs from 2018 through 2020. While there are seasonal fluctuations in inquiry volumes, the decrease in volume of inquiries is less pronounced than in former CBAs. The sharp decrease in inquiry volume in Q2 of 2020 corresponds with the start of the PHE. Following the start of the PHE there was a dramatic decrease in the volume of inquiries (Figure 6).

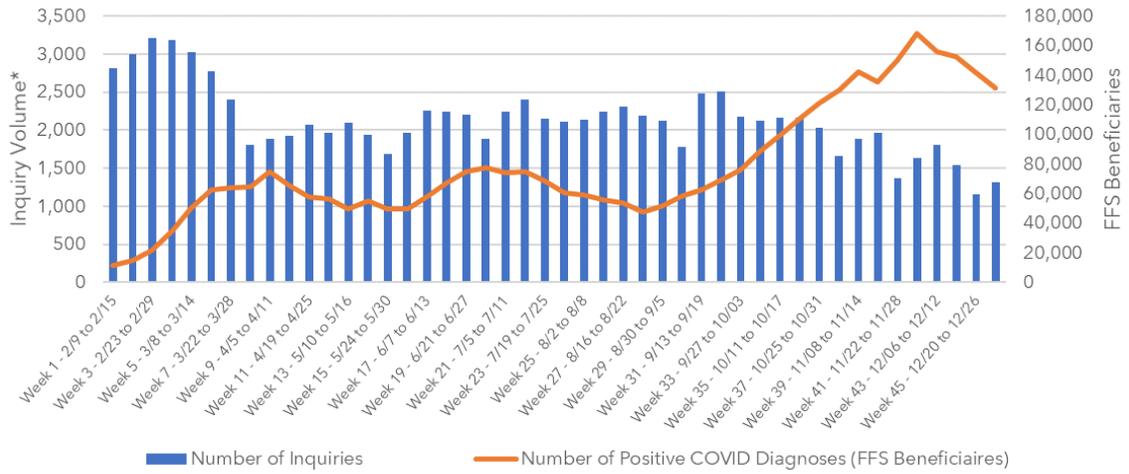
Figure 5: Inquiry Volume in Non-CBAs, 2018-2020



Data from Q4 2020 unavailable.

Source: 1-800-MEDICARE

Figure 6: Total Inquiry Volume During the PHE (former CBAs and non-CBAs for all DMEPOS CBP product categories)



* Inquiry volume refers to inquiries about products previously included in the DMEPOS CBP.
 Source: 1-800-MEDICARE



CMS Non-discrimination Notice and Communication Accessibility Provisions for Individuals with Disabilities

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1. Call us:

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For the Health Insurance Marketplace²⁶: 1-800-318-2596. TTY: 1-855-889-4325

2. Email us: 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.

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By phone: Call 1-800-368-1019. TTY users can call 1-800-537-7697.

In writing: Send information about your complaint to:

Office for Civil Rights

U.S. Department of Health and Human Services

200 Independence Avenue, SW

Room 509F, HHH Building

Washington, D.C. 20201

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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 and Notes

- ¹ Centers for Medicare & Medicaid Services. (2020, March 17). *Medicare Telemedicine Health Care Provider Fact Sheet*. Retrieved March 24, 2021, from <https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet>.
- ² Centers for Medicare & Medicaid Services. (n.d.). *Competitive Acquisition Ombudsman (CAO)*. Retrieved March 24, 2021, from [https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Competitive Acquisition Ombudsman](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Competitive%20Acquisition%20Ombudsman).
- ³ Centers for Medicare & Medicaid Services. (2019, March 8). *DMEPOS Competitive Bidding Round 2021 Fact Sheet*. Retrieved March 24, 2021, from <https://www.cms.gov/newsroom/fact-sheets/dmepos-competitive-bidding-round-2021>.
- ⁴ Centers for Medicare & Medicaid Services. (2020, April 13). *Press Release: CMS News Alert April 13, 2020*. Retrieved March 24, 2021, from <https://www.cms.gov/newsroom/press-releases/cms-news-alert-april-13-2020>.
- ⁵ Centers for Medicare & Medicaid Services. (2020, October 27). *Round 2021 DMEPOS Competitive Bidding Program Single Payment Amounts and Contract Offers*. Retrieved March 24, 2021, from <https://www.cms.gov/files/document/round-2021-dmepos-cbp-single-payment-amts-fact-sheet.pdf>.
- ⁶ Coronavirus Aid, Relief, and Economic Security Act, §§ 116-136-3212-3712 et seq. (2020). See <https://www.congress.gov/116/plaws/publ136/PLAW-116publ136.pdf>
- ⁷ U.S. Department of Health and Human Services. (2021, January 21). *Secretary Azar declares public health emergency for United States for 2019 novel coronavirus*. Retrieved March 24, 2021, from <https://www.hhs.gov/about/news/2020/01/31/secretary-azar-declares-public-health-emergency-us-2019-novel-coronavirus.html>.
- ⁸ Coronavirus Aid, Relief, and Economic Security Act, §§ 116-136-3212-3712 et seq. (2020). See <https://www.congress.gov/116/plaws/publ136/PLAW-116publ136.pdf>
- ⁹ Department of Health and Human Services. (2020, November 4). *Proposed Rule: Medicare Program; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policy Issues and Level II of the Healthcare Common Procedure Coding System (HCPCS)*. Federal Register. Retrieved April 3, 2021, from <https://www.govinfo.gov/content/pkg/FR-2020-11-04/pdf/2020-24194.pdf>. See pg. 70370; Section II, Subsection C.
- ¹⁰ 42 CFR § 414.210(g)(9). See <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-414/subpart-D/section-414.210>
- ¹¹ Centers for Medicare & Medicaid Services. (2020, October 27). *Round 2021 DMEPOS Competitive Bidding Program Single Payment Amounts and Contract Offers*. Retrieved March 24, 2021, from <https://www.cms.gov/files/document/round-2021-dmepos-cbp-single-payment-amts-fact-sheet.pdf>.
- ¹² Coronavirus Aid, Relief, and Economic Security Act, §§ 116-136-3212-3712 et seq. (2020). See <https://www.congress.gov/116/plaws/publ136/PLAW-116publ136.pdf>
- ¹³ The CARES Act increased adjusted fee-schedule amounts for certain DME in non-rural, contiguous non-CBAs to a 75%/25% blended rate.
- ¹⁴ Centers for Medicare & Medicaid Services. (2022, August 18). *Durable Medical Equipment, Prosthetics, Orthotics and Supplies: CMS Flexibilities to Fight COVID-19*. Retrieved April 6, 2023, from <https://www.cms.gov/files/document/durable-medical-equipment-prosthetics-orthotics-and-supplies-cms-flexibilities-fight-covid-19.pdf>
- ¹⁵ 42 CFR § 414.210(g)(9). See <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-414/subpart-D/section-414.210>

¹⁶ Department of Health and Human Services. (2020, November 4). *Proposed Rule: Medicare Program; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policy Issues and Level II of the Healthcare Common Procedure Coding System (HCPCS)*. Federal Register. Retrieved April 3, 2021, from <https://www.govinfo.gov/content/pkg/FR-2020-11-04/pdf/2020-24194.pdf>. See pg. 70370; Section II, Subsection C.

¹⁷ This rule proposed making the 50/50 blended rates in these areas permanent.

¹⁸ 42 CFR § 414.210(g)(10). See <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-414/subpart-D/section-414.210>

¹⁹ Department of Health and Human Services. (2018, November 14). *Final Rule: 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*. Federal Register. Retrieved April 11, 2023, from <https://www.govinfo.gov/content/pkg/FR-2018-11-14/pdf/2018-24238.pdf>. See pg. 57028; Section VI, Subsection B, Part 1

²⁰ About BFCC-QIOs. (2019, April 02). Retrieved March 24, 2021, from <https://qioprogram.org/about>.

²¹ Disasters in each county that occurred in 2020 are defined as per the FEMA declaration date in <https://www.fema.gov/openfema-data-page/disaster-declarations-summaries-v2>. Some disasters have an incident date in 2020 but were not declared a disaster until 2021; those are excluded. Number of DME users are obtained from the CMS Integrated Data Repository (IDR) by calculating number of unique beneficiaries enrolled in Part A and Part B who had at least one paid DME claim (claim type 82) in 2020. Number of FFS enrollees in each disaster-affected county were calculated from Medicare Enrollment Dashboard (<https://data.cms.gov/collection/cms-program-statistics>).

²² Disasters in each county that occurred in 2020 are defined as per the FEMA declaration date in <https://www.fema.gov/openfema-data-page/disaster-declarations-summaries-v2>. Some disasters have an incident date in 2020 but were not declared a disaster until 2021; those are excluded.

²³ Centers for Medicare & Medicaid Services. (2019, June). *Getting Medical Care & Prescription Drugs in a Disaster or Emergency Area*. Retrieved March 24, 2021, from <https://www.medicare.gov/Pubs/pdf/11377-Care-Drugs-Disaster-Emergency.pdf>.

²⁴ Centers for Medicare & Medicaid Services. (n.d.). *Office of Program Operations & Local Engagement*. Retrieved March 24, 2021, from <https://www.cms.gov/about-cms/cms-leadership/office-program-operations-and-local-engagement>.

²⁵ A temporary gap in the DMEPOS CBP began on January 1, 2019, and competitive bidding contracts expired. See: Department of Health and Human Services. (2018, November 14). *Final Rule: 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*. Federal Register. Retrieved April 11, 2023, from <https://www.govinfo.gov/content/pkg/FR-2018-11-14/pdf/2018-24238.pdf>. See pg. 57028; Section VI, Subsection B, Part 1

²⁶ Health Insurance Marketplace® is a registered trademark of the Department of Health and Human Services.