

FY 2012-2016

Report to Congress



From the Competitive Acquisition Ombudsman for the Durable Medical Equipment, Prosthetics, Orthotics, And Supplies Competitive Bidding Program

A MESSAGE FROM THE OMBUDSMAN

I am pleased to present the Competitive Acquisition Ombudsman's (CAO's) activities for fiscal years (FYs) 2012–2016 in this Report to Congress and the Secretary of the U.S. Department of Health & Human Services. Based on my interactions with stakeholders, this 5-year period had successes and challenges for suppliers participating in the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (the Program), which expanded from 2.6 million fee-for-service (FFS) beneficiaries in nine initial competitive bidding areas (CBAs) in 2011 to approximately 20.3 million beneficiaries in a total of 126 CBAs in 2016. I also received feedback from beneficiaries in this 5-year period, which I discuss later in this report. The National Mail-Order Program for diabetes testing supplies was also implemented during this time and was made available to 34 million Medicare FFS beneficiaries. While these expansions did not occur without challenges, the Centers for Medicare & Medicaid Services (CMS) listened to the concerns raised by stakeholders and beneficiaries and worked to resolve them using its casework management process to respond to inquiries and complaints and ensure that medical needs were met. To address many of the concerns received by suppliers and beneficiaries during this period, the Agency finalized changes to the Competitive Bidding Program, effective January 1, 2019, to ensure continued and improved sustainability of the Program, which supports participating suppliers, and access and service for beneficiaries.¹

As the CAO, I heard feedback from stakeholders about the application of Medicare DMEPOS supplier enrollment and payment rules in CBAs. As part of my mission, I shared the perspectives of Medicare beneficiaries, suppliers, and other Program stakeholders with CMS, as appropriate, and worked with CMS components to collect, analyze, and report data, and support efforts to develop new educational resources or improve existing ones. As detailed in this report, we addressed supplier challenges in CBAs with Medicaid provider enrollment and payment rules and state payment processes for dual eligible Medicare-Medicaid beneficiaries, and we educated discharge planners on the CMS inquiry and complaint process. I also collaborated with the Medicare Beneficiary Ombudsman (MBO) to address broader Medicare program concerns heard from beneficiaries, suppliers, and providers within CBAs. These concerns related to wheelchair repair policies, continuous positive airway pressure (CPAP) devices, and supplier concerns about increased audits and transparency around the required paperwork for these items due to the volume of beneficiaries transitioning to these items. The latter two efforts are discussed in the FYs 2014–2016 MBO Report to Congress. Other issues and concerns I heard included difficulty locating suppliers, concerns about the quality of the products or services, timeliness of delivery and customer service given by suppliers. Supplier concerns were in regards to the impact of competitive bidding reimbursement on furnishing products and services within the CBA, and concerns about bid winners adhering to contract requirements.

I thank our partners and stakeholders and the many CMS components, particularly OHI, that worked with me to support CMS implementation of the Program. We understand that we must continue to perform our due diligence to execute Medicare's mission of providing access to quality, affordable health care coverage to beneficiaries. I look forward to continuing this work to address beneficiary and other stakeholder needs and considerations.

/Tangita Daramola/
Competitive Acquisition Ombudsman

ABOUT THE OMBUDSMAN

The CAO responds to inquiries and complaints about the application of the Program from suppliers and individuals in accordance with Section 1847 of the Social Security Act.² These stakeholders include contract suppliers of competitively bid DMEPOS (including diabetes testing supplies), beneficiaries who use these items, health care providers and hospital case managers involved in the chain of care for these beneficiaries, and noncontract suppliers who have concerns about the impact of the Program on the industry in their areas.³ The CAO also works with CMS components to facilitate responses to stakeholder concerns.

With eight years of experience as the CAO, Tangita Daramola understands firsthand the complexities of the Program. Prior to being named the CAO, she served as the senior advisor to the first MBO, with whom she worked to establish the requirements for ombudsman services within CMS and develop complaint data reporting mechanisms for the Medicare Prescription Drug Program. She also served as the director of the Division of Beneficiary Inquiry Trends and Analysis, where she was instrumental in establishing more effective national customer service standards for written and electronic complaints and inquiries.

ABOUT THE DMEPOS COMPETITIVE BIDDING PROGRAM

The Round 1 Rebid contracts and single payment amounts became effective in January 2011. In general, CMS established the Program with the goal of making payment amounts more reflective of what it costs to furnish durable medical equipment (DME), while maintaining access to quality DME. In Round 2 of the Program, which began in 2013, CMS expanded the Program into additional areas of the country and added the National Mail-Order Program for diabetes testing supplies. The Program, combined with other CMS fraud, waste and abuse initiatives, is saving approximately \$2 billion per year. In FY 2015, CMS eliminated multistate CBAs, so beginning with the July 2016 Round 2 Re compete contracts, contract suppliers no longer needed to meet licensure requirements in multiple states in order to serve a single CBA.

In November 2018, CMS issued a final rule implementing changes to the Program to better align it with current market pricing strategies and to address concerns raised by suppliers and beneficiaries about access to items and services.⁴ The rule established changes to bidding and pricing methodologies under the Program, and addressed adjustments to DMEPOS fee schedule amounts using information from competitive bidding for items furnished from January 1, 2019 through December 31, 2020. Effective January 1, 2019, there is a two-year delay in the bidding program, and beginning January 1, 2021, the single payment amount for the lead item within each product category will be set at the maximum winning bid for the lead item rather than the median of winning bids. For the rest of the items within the product category, the single payment amounts will be determined by multiplying the single payment amount for the lead item by a relative ratio. These changes use market-oriented approaches to simplify the Program and ensure long-term sustainability.

Competitive Bidding Areas as of FY 2016



SUMMARY OF STAKEHOLDER CONCERNS

Throughout this reporting period, the CAO heard ongoing concerns from diverse stakeholders regarding access to DMEPOS items and services after the start of the Program. Reported supplier concerns focused on the challenges of providing DMEPOS under significantly reduced reimbursement and increased CMS reviews and audits. Beneficiaries and other stakeholders reported access issues in CBAs centered on delays in DMEPOS delivery, difficulty locating suppliers of some DMEPOS items, and service quality. The root causes of these issues varied and included the need for more precise medical necessity documentation to meet Medicare payment requirements, increased claim reviews and audits for suppliers now serving larger populations, supplier non-compliance with contract requirements, and the need for enhanced Medicare–Medicaid coordination at the state level. These concerns were resolved through a combination of casework, supplier compliance oversight, and educational activities. Examples of DMEPOS access concerns reported to the CAO by beneficiaries, advocates, health care providers, discharge planners, and DMEPOS suppliers included:

- Difficulty obtaining timely, quality DMEPOS delivery for patients being discharged from acute care facilities.
- Delayed and inaccurate payments by some state Medicaid programs.
- Difficulty locating contract suppliers that carried the brand of diabetes testing supplies used.
- Feeling pressured by contract suppliers to switch diabetes testing supply brands when the supplier did not carry the brand used.
- Difficulty obtaining liquid oxygen including: notification that a contract supplier would no longer supply liquid oxygen, refusal by another contract oxygen supplier to accept new patients who required liquid oxygen, and changes made by another contract supplier to the oxygen modality being provided.
- Difficulty locating contract suppliers to provide infusion pumps among those listed in the CMS Medicare Supplier Directory as providers of this product.
- Timely DME delivery by out-of-state suppliers with no in-state, physical presence.

Selected concerns are detailed in the following sections. Additional concerns regarding delays in obtaining wheelchair repairs and CPAP devices in CBAs are included in the FYs 2014–2016 MBO Report to Congress. Although some of these concerns are not specific to competitive bidding, they were raised by stakeholders in CBAs.

SELECT DMEPOS CONCERNS

DMEPOS Access at Hospital Discharge

Discharge planners and providers reported concerns about beneficiary access to DMEPOS products and services upon discharge from health facilities.

In FY 2015, the CAO received complaints from multiple stakeholders including a supplier organization, an integrated health system, a specialty hospital, and a regional hospital association representing 25 hospitals regarding alleged delays in DMEPOS delivery upon beneficiary discharge, incorrect or incomplete deliveries, and perceptions of poor customer service. The complaints originated from CBAs in the metropolitan areas of McAllen-Edinburg-Mission, Texas; Minneapolis–St. Paul, Minnesota; Denver, Colorado; Chicago, Illinois;

and northern California. In addition, discharge planners told the CAO that they did not know how to communicate their complaints about the Program to CMS on a regular basis.

The CAO brought these reports to appropriate CMS components. CMS conducted an analysis of inquiries and complaints to 1-800-MEDICARE from northern California beneficiaries in 2015, which showed that most were related to locating DMEPOS items and suppliers that carried specific products. CMS Regional Office (RO) staff serving the area met with the hospital association to discuss concerns the hospital association raised in obtaining DME, and Competitive Bidding Implementation Contractor (CBIC) staff researched the matter in detail. CMS Center for Medicare (CM) and RO staff also assessed suppliers in CBAs where these inquiries and complaints arose, and they met with the

regional hospital association to clarify how to communicate concerns to CMS. At stakeholder engagement events, the CAO clarified stakeholder concerns and provided guidance on the Medicare inquiry and complaint process, including how to contact Competitive Bidding Liaisons and make calls on behalf of beneficiaries through 1-800-MEDICARE, and the CAO explained program and supplier requirements and CMS oversight. The CAO also provided materials to hospital staff that could be included with discharge information for beneficiaries with written orders for DMEPOS and encouraged discharge planners to contact the 1-800-MEDICARE call center with any inquiries or complaints.

In FY 2016, the CAO and representatives from CM, the CMS Center for Program Integrity (CPI), OHI, the RO, the CBIC, and the Jurisdiction D Durable Medical Equipment Medicare Administrative Contractor (DME MAC) held a roundtable discussion with providers, representatives of a state supplier organization, and a state hospital association to clarify continued reports from discharge planners about difficulty obtaining DMEPOS for beneficiaries being discharged. CMS discussed how to make inquiries and complaints to 1-800-MEDICARE, the Program rules, DMEPOS supplier standards enforcement processes, and how to educate providers on correctly completing required documentation for DME orders. Stakeholders provided feedback and suggested improvements and clarifications to existing CMS educational materials. Through this process, CMS identified opportunities to improve communication with discharge planners and providers.

Medicare-Medicaid Crossover Claim Denials

Claims for products and services provided to dual eligible Medicare-Medicaid beneficiaries are called “crossover claims” because Medicaid pays the Medicare cost-sharing portion.⁵

Medicare payment policies apply nationwide, while Medicaid payment policies and processes vary by state. In FY 2013 and FY 2014, contract DMEPOS suppliers contacted the CAO to discuss the delayed receipt of Medicaid copays and crossover-claim denials. Contract suppliers reported that some states denied crossover claims they had submitted because they were not enrolled in those states’ Medicaid programs or did not provide certain preferred products.

Contract suppliers also alleged that they were unable to obtain Medicaid copays for dual eligible Medicare-

Medicaid beneficiaries in certain states. The CAO and other CMS components investigated these reports and found that crossover-claim reimbursement problems were occurring in seven states. In these states, contract DMEPOS suppliers were not allowed to enroll in Medicaid programs, despite CMS guidance in an August 2013 Center for Medicaid and Children’s Health Insurance Program Services information bulletin.⁶ In December 2013, CMS issued a memorandum emphasizing that states must allow all Medicare-enrolled providers, including out-of-state providers, to enroll in their Medicaid programs for the purpose of processing DMEPOS claims. In September 2014, the CAO facilitated a meeting with the supplier that made the initial complaint to discuss continuing Medicaid enrollment challenges being reported in some states.

In December 2016, the CAO was informed that there were complaints about a contract supplier in Sacramento, California that would not provide hospital beds to dual eligible Medicare-Medicaid beneficiaries. The CBIC investigated and found that this supplier had ongoing difficulty enrolling in the state’s Medicaid program and, therefore, had referred dual eligible Medicare-Medicaid beneficiaries to other contract suppliers. The CMS Federal Coordinated Health Care Office facilitated conversations with the state’s Medicaid officials to discuss the issue of suppliers enrolling for the purpose of processing crossover claims. The CAO shared these issues with CMS program staff, who found no evidence of a negative impact on beneficiary mortality, hospitalization, or emergency room admission rates. However, there were noted sporadic increases in length of hospital stay, but these could not be attributed directly to the Program. Moving forward, the CAO will continue to monitor this issue by seeking input at outreach and engagement activities from supplier organizations, beneficiary advocates, ROs, and State Health Insurance Assistance Programs (SHIPs).

DMEPOS Access Protections under the Program

Contract suppliers in the Program are subject to specific contract requirements, including that they generally must provide all items in a product category for which they accept a contract to any beneficiary throughout the CBA. The anti-switching rule further protects beneficiary access to quality DMEPOS products and services. The anti-switching rule prohibits contract suppliers from influencing or incentivizing beneficiaries to switch from their preferred brand of glucose monitor and diabetes

testing supplies to another.⁷ During this reporting period, the CAO received inquiries and complaints from stakeholders indicating that some of these rules and requirements were not being followed. The CAO collaborated with other CMS staff to facilitate responses to their concerns. Case examples are highlighted below.

Case Example: Diabetes Testing Supply Brands

The number of complaints regarding mail-order diabetes testing supplies that were escalated from 1-800-MEDICARE to the CBIC and ROs peaked in FY 2014 (see graph on page 6). One reason beneficiaries cited for the complaints was difficulty locating a contract supplier that carried a particular brand of testing supply. After the launch of the National Mail-Order Program in July 2013, a national diabetes advocacy organization reported to the CAO that beneficiaries contended that they had received unclear or inaccurate information from contract suppliers about Medicare coverage of diabetes testing supplies and the rules around preferred/prescribed brands. The CAO met with mail-order suppliers to discuss this issue and raised the concern to appropriate CMS components for investigation in August 2013. Throughout 2014 and 2015, the CAO provided reminders and data trends on this issue at quarterly feedback sessions with mail-order contract suppliers. In March 2014, CMS staff who run the National Mail-Order Program attended the session and reminded suppliers of the anti-switching rule and the requirement to assist beneficiaries in locating a contract supplier that furnishes a specific brand or mode of delivery if the beneficiary's physician or treating practitioner prescribes a particular brand or mode of delivery that they do not carry. These types of complaints persisted through the end of FY 2016, although they were fewer in number.

Case Example: Liquid Oxygen

In March 2014, the CAO was notified by a beneficiary advocate that a contract supplier of oxygen products informed beneficiaries that it would no longer supply liquid oxygen after their next scheduled delivery dates. Shortly thereafter, beneficiary advocacy groups reported that a second contract supplier had begun refusing to accept new patients who required liquid oxygen. The CAO also worked with the MBO to bring this issue to CMS program staff. CM investigated the contract supplier in the initial complaint and found that the supplier sent "cessation of service" notices to beneficiaries in its CBAs. CM program staff then communicated directly with both oxygen contract suppliers to remind them of their

contractual obligations to supply all products under the oxygen product category as prescribed, including liquid oxygen. Following this CMS program action, CMS caseworkers confirmed that affected beneficiaries were able to obtain the products they needed.

In May 2015, the CAO received another report from beneficiary advocates that some contract suppliers said they would discontinue providing liquid oxygen and instead would switch beneficiaries to portable oxygen. The CAO provided the information to the appropriate CMS components, such as CPI. She also communicated available resources to advocates, such as the ability to file a complaint with the National Supplier Clearinghouse.

Throughout the reporting period, the CAO worked with advocates for beneficiaries who use oxygen to improve CMS educational resources by adding scenario-based examples of how beneficiaries can receive help with their inquiries and complaints about oxygen supplies and provided feedback to CMS. CMS updated online and printed materials, and the CAO and the CMS Office of Communications worked with ROs to further disseminate updated CMS educational materials about oxygen product rules and requirements to beneficiary advocates and SHIPs. The 1-800-MEDICARE call center began tracking all contacts mentioning the removal of liquid oxygen and reporting them to the CBIC. The CAO and OHI continue to monitor all oxygen-product inquiries and complaints, and report trends as appropriate.

Case Example: External Infusion Pumps

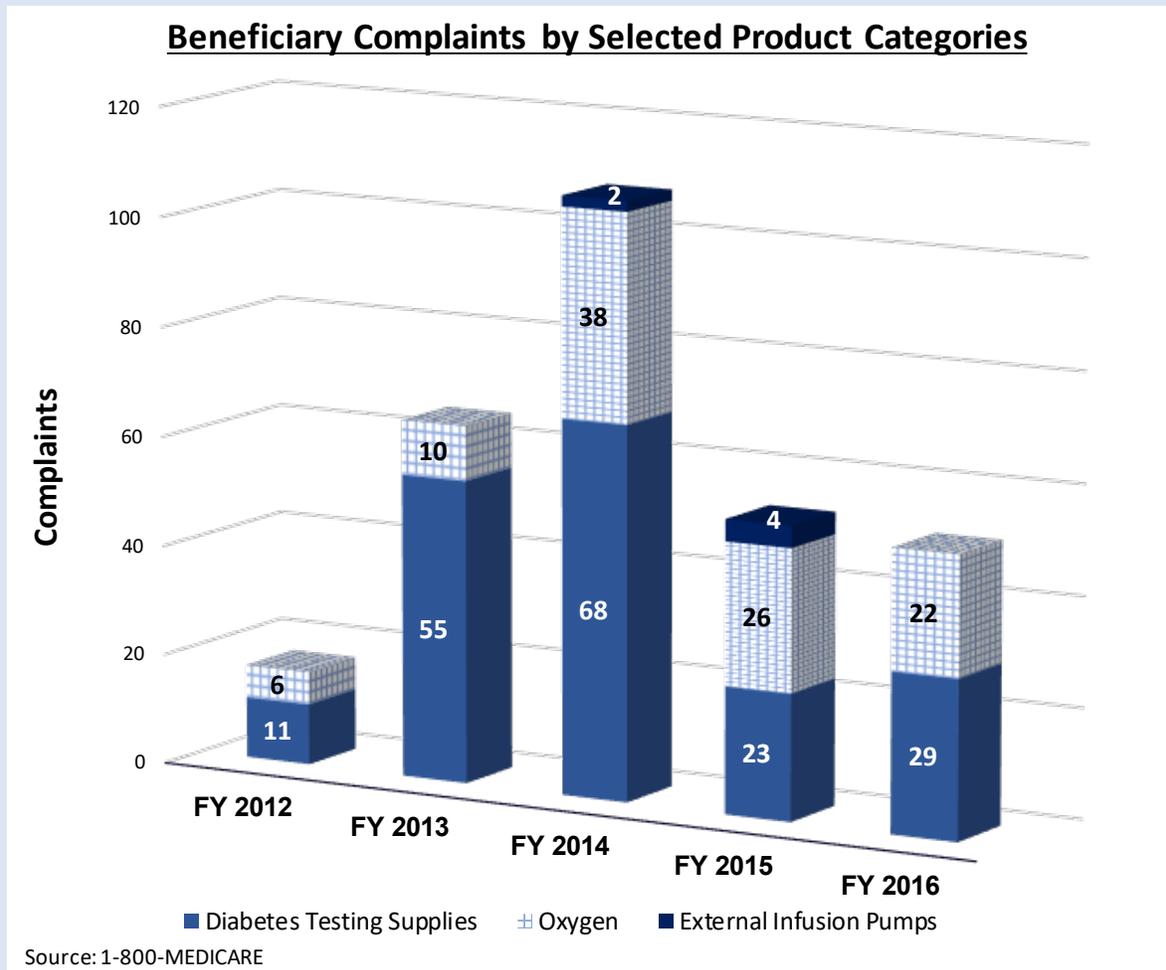
External infusion pumps were added to the Program in nine Round 1 Recompete CBAs on January 1, 2014. In the spring of 2014, the CAO received reports that some contract suppliers in a particular CBA told beneficiaries that they did not offer any insulin infusion pump products and suggested that the beneficiaries search for alternate suppliers on Medicare.gov. The stakeholder, a large insulin infusion pump manufacturer, further reported that approximately 50 beneficiaries had directly contacted them for assistance in obtaining insulin pumps and supplies due to the inability of contract suppliers in that CBA to provide them. The CAO notified the appropriate CMS components of these reports, including CM and the CMS Chief Medical Officer. The CBIC provided contract compliance reminders and education to contract suppliers in the CBA where the problem was reported. Also, in early 2015, a beneficiary advocate reported that approximately half of the

suppliers it contacted in the CBA where the complaints originated did not carry insulin pumps; of those that did, many only carried one brand. In both instances, CMS immediately investigated the reports using claims data and secret shopper calls. These investigations verified that the contract suppliers that were called would

provide the product. To evaluate different options for phasing in the drugs used with the infusion pumps, CMS excluded the External Infusion Pump product category from the Round 2 Recompete and Round 1 2017 competitions so that further analysis could be done.

BENEFICIARY COMPLAINT DATA : 1-800 MEDICARE BENEFICIARY COMPLAINT ESCALATIONS

Inquiry and complaint trends are captured from diverse stakeholders, and the CAO periodically conducts in-depth reviews of complaint details. During the reporting period, 633 total beneficiary complaints were escalated from 1-800-MEDICARE to the CBIC and ROs.⁸ This total includes complaints about wheelchair repairs and CPAP devices from beneficiaries in CBAs, which are discussed in the FYs 2014–2016 MBO Report to Congress because the root cause of the concern was not competitive bidding. The chart below shows the three product categories discussed in the case examples and accounted for 294 (46.4 percent) of all complaints received.

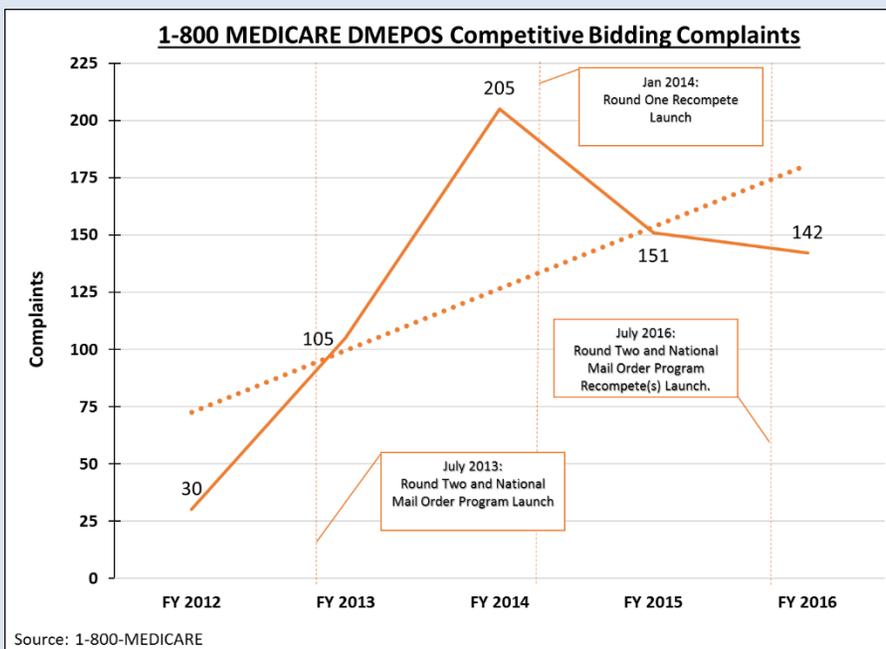
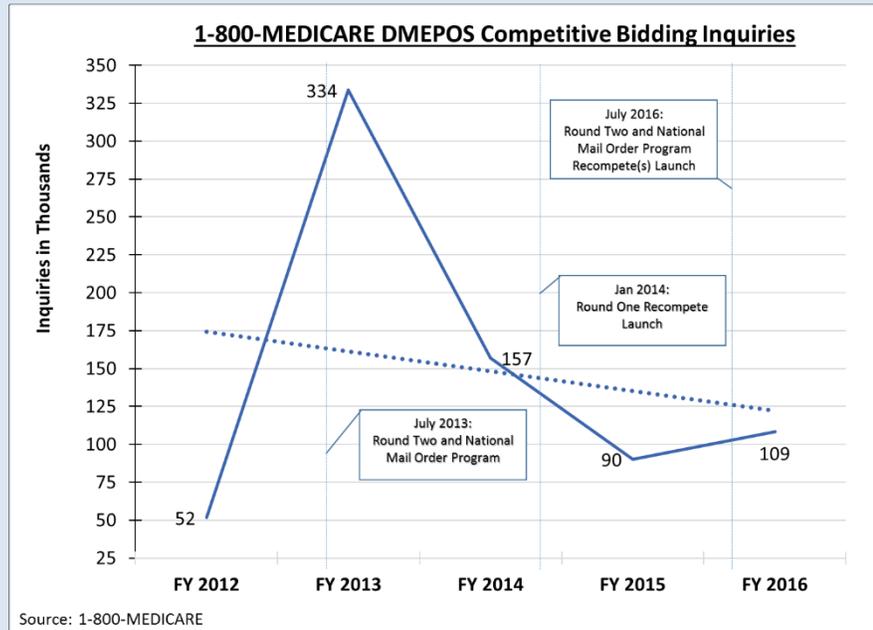


BENEFICIARY INQUIRY DATA : TRACKING DATA TRENDS

CMS customer service entities record and categorize data on inquiries and complaints they receive from beneficiaries, beneficiary caregivers, and other stakeholders. The CAO works with OHI data analysts to compile contact data about the Program from a variety of sources to track trends in inquiry and complaint topics that various customer service areas receive. These trends provide context and scope for topics that have come to the attention of CMS.

Over the 5-year reporting period, beneficiary inquiries to 1-800-MEDICARE trended down, while beneficiary complaints trended up.⁹ Increases and decreases in inquiries and complaints over the period coincided with the launch of Program rounds, which brought more beneficiaries into the Program and may have required some beneficiaries to change suppliers and seek assistance in that process. As time passed, beneficiaries became familiar with the Program and found new suppliers.

- Between FY 2012 and FY 2016, there were 741,056 inquiries related to the Program.
- 51% of the inquiries, or 376,373, were product related.
- The remaining 49%, or 364,683, were general inquiries.
- The dotted line represents a downward trend in DMEPOS inquiries from FYs 2012-2016.



- Between FY 2012 and FY 2016, 633 complaints were escalated from 1-800-MEDICARE.
- The reasons for complaints included locating a contract supplier, item quality or timeliness, and supplier customer service.
- Mail-order diabetes testing supplies averaged the highest number of complaints, with 37 complaints annually.
- The dotted line represents an upward trend in DMEPOS complaints from FYs 2012-2016.

CMS Accessibility & Nondiscrimination for Individuals with Disabilities Notice

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For the Health Insurance Marketplace®: 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 and Inquiries (OHI)
7500 Security Boulevard, Mail Stop S1-13-25
Baltimore, MD 21244-1850
Attn: Customer Accessibility Resource Staff

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

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

- ¹ 83 Fed. Reg. 56922 (Nov. 14, 2018). See <https://www.govinfo.gov/content/pkg/FR-2018-11-14/pdf/2018-24238.pdf>
- ² Social Security Act § 1847(f), 42 U.S.C. 1395w–3(f).
- ³ Ibid.
- ⁴ 83 Fed. Reg. 56922 (Nov. 14, 2018). See <https://www.govinfo.gov/content/pkg/FR-2018-11-14/pdf/2018-24238.pdf>
- ⁵ CMS.gov. (August 2, 2013). *CMCS Informational Bulletin: Medicare Competitive Bidding Program for Durable Medical Equipment and Coordination of Benefits for Beneficiaries Eligible for Medicare and Medicaid (Dual Eligibles)*. Retrieved on June 8, 2015, from <http://www.medicare.gov/federal-policy-guidance/downloads/CIB-08-02-2013.pdf>.
- ⁶ Ibid.
- ⁷ CMS.gov. (n.d.). *Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Competitive Bidding Program (DMEPOS CBP) National Mail-Order Competitions – Final Rulemaking (1503-P): Backgrounders*. Retrieved on April 17, 2017, from https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/downloads/mail_order_fact_sheet.pdf.
- ⁸ 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 FY 2014.
- ⁹ Total inquiries do not represent total phone calls. A person may ask several questions in one phone call, resulting in multiple contacts.

The website links provided were accessible at the time this report was developed. Please contact us if a reference website is now inactive and you would like to request a copy of the referenced material.

Please contact:

Centers for Medicare & Medicaid Services
Offices of Hearings and Inquiries (OHI)
7500 Security Boulevard, Mail Stop S1-13-25
Baltimore, MD 21244-1850

Your request should include:

- Your name, phone number, and the mailing address where we should send the materials.
- The footnote number and title of the reference materials you request.
- The format you need, like original publication, Braille, large print, or data/audio CD.