

Supporting Statement Part A
Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)
Competitive Bidding Program
CMS-10169, OMB 0938-1016

Note: This 2025 iteration proposes changes under CMS-1828-P and to reinstate OMB control number 0938-1016. We let the previously approved requirements and burden lapse as the requirements/burden were no longer relevant at the time of the December 31, 2021, expiration date and we wanted to avoid creating unnecessary confusion by soliciting comment on such outdated requirements and burden.

Background

Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“Medicare Modernization Act” or “MMA”) and mandated a phased-in approach to implement this program over the course of several years beginning in 2007 in 10 metropolitan statistical areas (MSAs). This statute specifically required the Secretary to establish and implement programs under which competitive bidding areas (CBAs) are established throughout the U.S. for contract award purposes for the furnishing of certain competitively priced items and services for which payment is made under Medicare Part B. This program is commonly known as the “Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP).”

On July 15, 2008, Congress delayed this program in section 154 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). MIPPA mandated certain changes to the Competitive Bidding Program.

As required by MIPPA, CMS conducted the evaluation of bids for the Round 1 Rebid in 2009. The Round 1 Rebid contracts and prices became effective on January 1, 2011. The Affordable Care Act (ACA), enacted on March 23, 2010, expanded Round 2 from 70 MSAs to 91 MSAs, which began in December 2011. CMS also began a round of the national mail-order of Diabetes Testing Supplies (DTS) at the same time as Round 2. The Round 2 and national mail-order contracts and prices were implemented on July 1, 2013.

Additionally, Section 1847(a)(1)(G) of the Social Security Act (the Act), added by section 522(a) of the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114-10) (MACRA), requires a bid surety bond for bidding entities beginning not earlier than January 1, 2017, and not later than January 1, 2019. Based on the passage of MACRA, we put forth proposed additions to §414.412, “Submission of bids under a competitive bidding program,” to add a new paragraph (h) that would allow CMS to implement section 1847(a)(1)(G) of the Act, as amended by section 522(a) of MACRA, to state that an entity may not submit a bid for a CBA unless, as of the deadline for bid submission, the entity has obtained a bid surety bond for the CBA. CMS published the proposed rule CMS-1651-P on June 30, 2016. The comment period on this rule closed on August 23, 2016. CMS published the final rule CMS-1651-F on November 4, 2016.

Round 2 Recompete and the national mail-order recompetete contracts became effective on July 1,

2016, and expired on December 31, 2018. After a temporary gap period in the DMEPOS CBP's implementation from 2019 through 2020, CMS consolidated the rounds to include all Round 1 and Round 2 competitive bidding areas, referred to as Round 2021.

Round 2021 included all prior competitively bid product categories (except for diabetes testing supplies), off-the-shelf (OTS) back braces and OTS knee braces, and non-invasive ventilators. The non-invasive ventilators product category was removed from Round 2021 prior to the awarding of contracts due to the novel COVID-19 pandemic. Later, all other product categories were removed from Round 2021, except for OTS back braces and OTS knee braces. Round 2021 contracts were effective January 1, 2021, through December 31, 30, 2023. As of January 1, 2024, there is another temporary gap period for the DMEPOS CBP until we complete the formal public notice and comment rulemaking process, and implement necessary changes to the DMEPOS CBP.

The most recent approval for this information collection request (ICR) was issued by the Office of Management and Budget (OMB) on December 7, 2018. That ICR included a "non-material or non-substantive change to a currently approved collection". We are now seeking approval to update our burden estimates to Form A and Form B to account for proposed updates to the DMEPOS CBP. The proposed updates include only requiring bidding entities to submit a credit report with a numerical credit score or rating during the bid window (the submission of a tax return extract, income statement, balance sheet, and statement of cash flows would no longer be required) to streamline the requirements and evaluation of the DMEPOS CBP financial standards, while still ensuring that suppliers offered contracts are financially stable enough to participate in the Medicare DMEPOS CBP for the duration of the contract performance period.

Additionally, the proposed updates include an attestation so suppliers can attest if they are a "small supplier" because bidding entities will no longer have to submit a tax return extract which was previously utilized to determine if bidding entities met the definition of a "small supplier" for purposes of the DMEPOS CBP. In addition, the proposed updates include adding an annual update factor to adjust the single payment amounts (SPAs) for the second and third year of a DMEPOS CBP contract performance period, so a bidding entity would no longer need to account for inflation and/or other potential future effects of price increases to provide certain DMEPOS.

Also, the proposed updates include using actual contract supplier utilization information from previous rounds of the DMEPOS CBP for product categories previously included in the DMEPOS CBP and information on current supplier utilization for new product categories included in the DMEPOS CBP to determine the number of contracts to award in each competitive bidding area (CBA) and product category combination (competition) in the DMEPOS CBP, so bidding entities would no longer have to determine the capacity they could furnish in each competition and then have to enter the applicable estimate(s) on its bid submission. Furthermore, the proposed updates include a new definition for a remote item delivery (RID) CBA that could be one nationwide CBA and include product categories that have not yet been included in the DMEPOS CBP.

The burden has been adjusted to account for expected number of respondents due to the proposed

updates to the DMEPOS CBP under this ICR. We intend to continue use of these forms on an ongoing basis.

A. Justification

1. Need and Legal Basis

Section 302 of the MMA amended section 1847 of the Act to require the implementation of the DMEPOS competitive bidding program. The Act provided the program requirements for the submission of bids in establishing payment rates and the awarding of contracts; provided the requirements for mergers and acquisitions; and a requirement for the Secretary to re-compete contracts not less often than once every three years. These regulations were published on April 10, 2007 (72 FR 17992).

2. Information Users

The information collected is used by CMS and the Competitive Bidding Implementation Contractor (CBIC) during the bid evaluation process for the selection of contract suppliers. All information submitted by the bidders is considered and evaluated.

Form A collects key business information to identify a bidder, the competitive bidding area(s) (CBA(s)) and product categories where the supplier chooses to bid, and pertinent information to support the supplier meets program eligibility requirements. A thorough analysis is performed of all information submitted to determine that the supplier has met all program requirements, including licensure, financial and quality standards. In addition, Form A provides instructions in accordance with §414.412(g), by allowing a bidder to attest that they have obtained a bid surety bond for each CBA for which they are submitting a bid. Bidders must upload a copy of each bid surety bond to the DMEPOS CBP's secure portal by the close of the bid window. Form A will also allow a bidder to attest if they are a small supplier (less than \$3.5 million or less in annual receipts including Medicare and non-Medicare revenue). Bidders must upload the applicable financial document(s) to the DMEPOS CBP's secure portal by the close of the bid window.

Form B contains key bid information including the bid price for each lead item, intent to subcontract services, and specific manufacturer and model information for each item. The manufacturer and model information is utilized to populate the Medicare Supplier Directory during the contract performance period. CMS utilizes the combined information from Form A and Form B to select winning bidders and establish the single payment amounts for competitively bid items.

3. Use of Information Technology

All bidders must submit their bidder information, bids, and signature(s) electronically into Form A and Form B using the DMEPOS CBP bidding system. This system allows suppliers to easily and consistently provide the necessary information. Bidders are allowed to make changes to their bids at any time prior to the close of the bid window, at which time bidders are required to complete, approve and certify their bids. The CBIC will use the appropriate technology to safely

obtain and secure the bidding information that is transmitted. Assistance and technical support is available to help bidders throughout the competitive bidding process. Bidders will be required to submit supporting documentation such as required financial documents (credit report with a numerical credit score and/or rating) and a copy of their bid surety bond(s) to the DMEPOS CBP's secure portal.

4. Duplication of Efforts

This information collection does not duplicate any other effort, and the information cannot be obtained from any other source.

5. Small Businesses

These information collections will impact small businesses. However, CMS has attempted to reduce the burden on small suppliers by requiring them to submit only those forms that are essential to implement the Program according to regulations. CMS has made an effort to minimize the burden associated with the process by publishing guidance with fact sheets, frequently asked questions, and providing online forms with checklists of other required documents.

In developing bidding and contract award procedures, section 1847 (b)(6)(D) of the Act requires us to take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in the Medicare DMEPOS CBP. Section 1847(b)(2)(A)(ii) of the Act also states that the needs of small suppliers must be taken into account when evaluating whether an entity meets applicable financial standards. We note that CMS has also implemented numerous regulatory provisions to reduce burden on small suppliers. These provisions are described in the April 10, 2007, and January 16, 2009, regulations and will remain in effect for future rounds.

6. Less Frequent Collection

Section 1847 of the Act requires suppliers to submit a bid for every new round of competitive bidding in order to be considered for the award of a contract. The Secretary is required to recompetes contracts not less often than once every three years. During the bidding process, each bidder will be required to submit one Form A. Bidders will be required to submit one Form B for each product category/competitive bidding area for which a bid is submitted. The statute provides no options for less frequent collection. Failure to collect this information will result in non-compliance with statutory requirements and the loss of billions of dollars in savings.

7. Special Circumstances

There are no special circumstances related to the collection of information for the Medicare DMEPOS CBP.

8. Federal Register/Outside Consultation

Federal Register

Serving as the 60-day notice, the NPRM (CMS-1828-P, RIN 0938–AV53) published in the Federal Register on July 2, 2025 (90 FR 29108). Comments must be received on/by August 29, 2025¹.

Outside Consultation

There was no outside consultation related to the collection of information for the Medicare DMEPOS CBP.

9. Payments/Gifts to Respondents

We will not be providing gifts or any payments (other than remuneration under the contract) to bidders.

10. Privacy

CMS will maintain the confidentiality of proprietary and financial information to the extent provided by law and will follow the procedure stated in 45 CFR 5.65. CMS will not share information about any bidder with other entities. However, an independent evaluator may be granted access to a bidder's information as permitted by law. Any reports that are created to evaluate the Medicare DMEPOS CBP will be reported in an anonymous or aggregate format. Bidder information may be reviewed as required by law by the GAO and the DHHS OIG, and by the Department of Justice (DOJ). CMS will request that any reports created to evaluate the Medicare DMEPOS CBP by the GAO and DHHS/OIG will report information in an anonymous or aggregate format.

All U.S. Federal Government contractor staff with access to bidder's information will be required to sign a statement agreeing to maintain the confidentiality of each bidder's information.

11. Sensitive Questions

There are no questions of a sensitive nature related to the collection of information for the DMEPOS CBP.

12. Burden Estimates

Wage Estimates

To derive average costs, we are using data from the U.S. Bureau of Labor Statistics' May 2024 National Occupational Employment and Wage Statistics for all salary estimates (<https://www.bls.gov/oes/tables.htm>). In this regard, the following table presents BLS' mean hourly wage, our estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and our adjusted hourly wage.

¹ See July 9, 2025 (90 FR 3021).

National Occupational Employment and Wage Estimates

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefits and Other Indirect Costs (\$/hr)	Adjusted Hourly Wage (\$/hr)
Administrative Services Manager	11-3012	52.11	52.11	104.22

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and other indirect costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Collection of Information Requirements and Associated Burden Estimates

Bidding Form A

Form A is used to identify the bidder. This form includes information for all locations that will be included with the bid(s). In preparation for the next round, this form will also provide new instructions in accordance with §414.412(h), allowing the bidder to attest that they have obtained a bid surety bond for each CBA for which they are submitting a bid.

We estimate the time to obtain a bid surety bond from a surety company (including contacting the company, filling out forms, submitting forms, filing paperwork, etc.) to be 11 minutes (0.2 hr). Additionally, we estimate that the time to assemble and complete the new bid surety bond section of Form A to be 5 minutes (0.08 hr). The time to submit the bid surety bond documentation is estimated to take an additional 5 minutes (0.08 hr).

Therefore, the total time to complete Form A is 8 hours and 21 minutes (8.35 hr). We have estimated the number of respondents (bidders) for the next round based on our experience from prior rounds of competition. Each bidder will be required to complete one Form A for each round in which it bids. This estimate is based on the time it takes a bidder to develop their business strategy on which CBAs and product categories to bid; obtain their bid surety bond(s); gather the required documents; and enter and review their information. It is anticipated that an Administrative Services Manager would have the requisite knowledge, access to information, and decision making authority related to a bidder's business operations necessary to formulate a bid.

We do not know the exact number of bidders who will bid in the next round; however, for purposes of this burden estimate, we will assume that the number of bidders will be roughly the same as in previous rounds of competition. We estimate there will be approximately 1,500 bidders in the next round and each bidder will complete Form A once for a total of 12,525 hours (1,500 respondents x 8.35 hr/response) at a cost of \$1,305,356 (12,525 hr x \$104.22/hr). When annualized over OMB's three-year approval period we estimate an annual burden of

4,175 hr (12,525 hr/3 years) and \$435,119 (\$1,305,356/3 years).

Form A			
Round	Total Number of Bidders	Total Time (hr)	Total Cost (\$)
Next round	1,500	12,525	1,305,356
Annualized Total	500	4,175	435,119

Bidding Form B

Bidders will use Form B to submit bids for items included in the Program. This form will be completed once for each CBA and product category combination with an estimated completion time of 3 hours. Total completion time assumes the time it takes a bidder to develop their bid amount and enter the applicable information into Form B.

For the next round, we do not know how many bids will be submitted; however, for purposes of this estimate, we would assume the average bidder would bid in 5 CBAs in 7 product categories for an average total of 35 Form Bs. We expect the number of hours to complete Form B to decrease based on the removal of the expansion plan section, as well as the proposed change in bidding methodology to move to lead item pricing as published in CMS-1691-P. Specifically, the expansion plan section is being removed from Form B to reduce the burden for bidders by streamlining the bidding process. The proposed change in the bidding methodology to move to lead item pricing will require bidders to only submit a single bid for an entire product category, instead of multiple bids (which can be over 100 for some product categories).

It is anticipated that an Administrative Services Manager would have the requisite knowledge, access to information, and decision making authority related to a bidder's business operations necessary to formulate the bid.

Assuming 1,500 bidders participate in the next round of the Program, and each bidder completes 35 Form Bs, there will be estimated 52,500 Form Bs (1,500 respondents x 35 forms/response) submitted taking an estimated 157,500 hours (52,500 submissions x 3 hr/submission) at a cost of \$16,414,650 (157,500 hr x \$104.22/hr). When annualized over OMB's three-year approval period we estimate an annual burden of 52,500 hr (157,500 hr/3 years) and \$5,471,550 (\$16,414,650/3 years).

Form B				
Round	Total Estimated Number of Bidders	Total Estimated Number of Form Bs Based on 35 Per Bidder	Total Time (hr)	Total Cost (\$)
Next round	1,500	52,500	157,500	16,414,650
Annualized Total	500	17,500	52,500	5,471,550

Proposed (CMS-1828-P) Changes

See section 15, below.

Annual Burden Summary

Form	No. Respondents	Annual Responses	Annual Time (hr)s	Annual Cost (\$)
FORM A				
Form A (Active)	500	500	4,175	435,119
CMS-1828-P	2,333	1,333	(2,542)	(264,928)
<i>Subtotal</i>	2,833	1,833	1,633	170,191
FORM B				
Form B (Active)	500	17,500	52,500	5,471,550
CMS-1828-P	2,833	20,333	(9,666)	1,007,425
<i>Subtotal</i>	3,333	37,833	42,834	6,478,975
Total	6,166	39,666	44,467	6,649,166

13. Capital Costs

The information required is information that is readily available to DMEPOS suppliers, and they should have the equipment necessary to collect and furnish the information. The equipment needed to process these forms is the same equipment that would be needed to provide routine business functions. As a result, there should be no extra capital cost to respondents for recordkeeping resulting from the collection of this information.

14. Cost to Federal Government

The government incurs approximate annual costs of \$1.5 million for contractor work to operate and maintain the DMEPOS CBP bidding system. These costs are more than offset by the savings resulting from DMEPOS CBP implementation. First launched in 2011 in nine metropolitan statistical areas and since expanded to 130 competitive bidding areas, Medicare has saved an estimated \$11 billion from lower payment for 16 categories of DMEPOS items and services, with beneficiaries saving from lower cost sharing. In addition to the savings obtained in the competitive bidding areas, adjustments made to fee schedule amounts paid in non-competitive bidding areas based on pricing from the DMEPOS CBP has approximately doubled these savings. Payment has generally declined 40 percent compared to the traditional fee schedule methodology.

15. Changes to Burden

Serving as the 60-day notice, the NPRM (CMS-1828-P, RIN 0938-AV53) published in the

Federal Register on July 2, 2025 (90 FR 29108). When ready, the finalized changes (under the CY 2026 HH PPS final rule) will be submitted to OMB for reinstatement with change. We let the previously approved requirements and burden lapse as the requirements/burden were no longer relevant at the time of the December 31, 2021, expiration date and we wanted to avoid creating unnecessary confusion by soliciting comment on such outdated requirements and burden.

Numerous variables can impact burden and may be unique to each round of the Medicare DMEPOS CBP. Variables contributing to burden differences between rounds include the number of product categories in the round, resulting in the number of bidders and the number of bids submitted. Rulemaking can also contribute to burden differences between rounds.

The total overall burden for this package has decreased as a result of several proposals outlined in this Notice of Proposed Rulemaking. Below we've described the specific proposals and the anticipated changes in burden based on historical data and/or estimates from past experience. We are revising this package to adjust the burden accordingly.

a. ICRs for the Submission of Financial Documents (§414.414(d))

Per § 414.414(d), each bidding entity must submit along with its bid the applicable covered documents specified in the request for bids. As discussed in section VII. of this proposed rule, based on internal review we are proposing to streamline the requirements and evaluation of the DMEPOS CBP financial standards, while still ensuring that suppliers offered contracts are financially stable enough to participate in the Medicare DMEPOS CBP for the duration of the contract performance period. Specifically, CMS is proposing to only require bidding entities to submit a credit report with a numerical credit score or rating during the bid window. The submission of a tax return extract, income statement, balance sheet, and statement of cash flows would no longer be required, which would significantly reduce the time it takes a bidding entity's Administrative Services Manager to assemble and upload financial documents during the bidding process by minus 5 hours and 15 minutes (from 8 hours and 21 minutes to 3 hours and 6 minutes).

As a result of the decreased covered document submission requirement CMS would no longer be able to utilize revenue data from the bidding entity's tax return to determine if it meets the definition of a "small supplier" in the DMEPOS CBP (that is, a bidding entity that generates gross revenue of \$3.5 million or less in annual receipts including Medicare and non-Medicare revenue). To address this, CMS is proposing to add a question to Form A (Application for DMEPOS Competitive Bidding Program) that would allow a bidding entity to attest whether it meets the definition of a small supplier.

While we do not know the exact number of bidders that would bid in the next round, for the purpose of scoring the PRA-related impact of the aforementioned changes, we expect that the number of bidders would increase by approximately 1,000 bidders (from 1,500 to 2,500 bidders) due to the proposals discussed in section VIII.B.7.b., c., and d. of this proposed rule. As a result, we estimate there would be approximately 833.33 bidders annually (2,500 bidders/3 years) in the next round and each bidder would complete Form A.

We expect the burden associated with the new attestation requirement to be minimal since suppliers should already be aware of their current revenue levels. That said, for the purpose of scoring the PRA-related impact of this rule's proposed changes, we estimate that it would take (on average) 6 minutes (0.1 hr) at \$104.22/hr for a bidding entity's Administrative Services Manager to complete the attestation question. In aggregate, we estimate an additional annual burden of 83 hours (833.33 bids/year x 0.1 hr/bid) at a cost of \$8,650 (83 hr x \$104.22/hr) for completing the attestation in Form A.

With regard to the reduction in the number of covered documents that bidding entities are required to submit during the bid window, we estimate 500 bidders (1,500 active bids per year/3 years) since this is the revision of an existing (active) requirement. In aggregate, we estimate an annual savings of minus 2,625 hours (500 bids x -5.25 hr/bid) and minus \$273,578 (-4,375 hr x \$104.22/hr) for completing Form A.

Overall, we estimate an annual savings of minus 2,542 hours (83 hr – 2,625 hr) and minus \$264,928 (\$8,650 - \$273,578).

b. ICRs for Adjustments to Single Payment Amounts (SPAs) (§ 414.408(b))

As discussed in section VII. of this proposed rule, based on internal review and industry feedback, we propose to revise § 414.408(b) which currently does not allow changes to the SPAs for the duration of a round of the DMEPOS CBP. Specifically, we propose to add an annual update factor to adjust the SPAs for the second and third year of a DMEPOS CBP contract performance period by the same annual covered item update factors applied to the fee schedule amounts for the items in non-CBAs. Therefore, when a bidding entity is formulating its bid amounts at the time of bidding and entering it on Form B (Bidding Form), a bidder would no longer need to account for inflation and/or other potential future effects of price increases to provide certain DMEPOS.

We expect that the change would reduce the amount of time for an Administrative Services Manager to complete Form B by approximately 24 minutes (0.4 hr) (from 3.0 hr to 2.6 hr).

While we do not know the exact number of bidders that would bid in the next round, for the purpose of scoring the PRA-related impact of the aforementioned changes, we expect that the number of bidders would increase by approximately 1,000 bidders (from 1,500 to 2,500 bidders) due to the proposals discussed in section VIII.B.7.b., c., and d. of this proposed rule. We also expect that the average bidder would bid in 22 competitions (our active burden estimates 35 competitions) for a difference of minus 13 competitions.

In aggregate, we estimate savings of minus 14,500 hours [CURRENT (1,500 bidders x 35 bids/bidder x 3 hr/bid) - PROPOSED (2,500 bidders x 22 bids/bidder x 2.6 hr/bid)] and minus \$1,511,190 (14,500 hr x \$104.22/hr) for completing Form B. Annually, this would amount to a savings of approximately 4,833 hours (14,500 hr/3 yr) and \$503,730 (\$1,511,190/3 yr).

c. ICRs for Determining the Number of Contracts Awarded (§ 414.414(h))

As discussed in section VII. of this proposed rule, based on internal review we are proposing to revise § 414.414(h) for how CMS determines the number of DMEPOS CBP contracts to award to DMEPOS bidding entities. Specifically, we propose to use contract supplier utilization information from previous rounds of the DMEPOS CBP for product categories previously included in the DMEPOS CBP as well as information on current supplier utilization for new product categories. With this change, bidding entities would no longer have to determine the capacity that they could furnish in each competition and enter the applicable capacity estimate(s) on Form B of their bid submission.

We believe it took a supplier's Administrative Services Manager approximately 90 minutes (1.5 hr) (out of 3.0 hr/bid) to determine their estimated capacity in each competition and entering it on each Form B.

As previously mentioned, while we do not know the exact number of bidders that would bid in the next round, for purposes of scoring the PRA-related impact of this rule, we expect that the average bidder would bid in 22 competitions. While we previously estimated that the average bidder would complete 35 Form B's (5 CBAs x 7 product categories), we believe that the additional 1,000 bidders would only submit, on average, bids for approximately two competitions (two Form Bs) in the next round of the DMEPOS CBP, reducing the average number of Form B submissions by 13 (from 35 to 22 competitions) per bidder.

In aggregate, we estimate savings of minus 75,000 hours [CURRENT (1,500 bidders x 35 bids/bidder x 3 hr/bid) - PROPOSED (2,500 bidders x 22 bids/bidder x 1.5 hr/bid)] and minus \$7,816,500 (75,000 hr x \$104.22/hr) for completing Form B. Annually, this would amount to a savings of approximately 25,000 hours (75,000 hr/3 yr) and \$2,605,500 (\$7,816,500/3 yr).

d. ICRs for the Remote Item Delivery (RID) Competitive Bidding Program and Revising the Definition of Item Related to Medical Supplies (§ 414.402)

As discussed in section VII. of this proposed rule, based on internal review, under § 414.402, we are proposing to create a new definition of RID to mean a competitive bidding program wherein contract suppliers are responsible for furnishing remote item delivery items under the product category to all Medicare beneficiaries regardless of where they live in the CBA. The CBA could be one nationwide CBA that includes all areas (all States, territories, and the District of Columbia) or a CBA covering a specific region of the country."

As discussed in section VII. of this proposed rule, because we are also proposing to specify that ostomy, tracheostomy, and urological supplies are medical supplies mandated for inclusion under the DMEPOS CBP by section 1847(a)(2)(A) of the Act, we expect that both changes would result in an increase in burden as suppliers would potentially have additional CBAs and product categories in which they could bid.

While we do not know the exact number of bidders that would bid in the next round, for the purpose of scoring the PRA-related impact of the aforementioned changes, we expect 2,500 bidders (an increase of 1,000 bidders) due to the proposals discussed in section VIII.B.7.b., c., and d. of this proposed rule. As a result, we estimate there would be approximately 833.33

bidders annually (2,500 bidders/3 years) in the next round and each bidder would complete 22 Form Bs (a decrease of 13 competitions/bidder).

Because of the new competitions (product category and CBA combinations) being added into the DMEPS CBP, we estimate that it would take a supplier's Administrative Services Manager an additional 1 hour at \$104.22/hr to develop its bid amount for each product category that they bid and an additional 6 minutes (0.1 hr) to complete Form B.

In aggregate, we estimate a burden of 20,167 hours (833.33 bidders/year x 22 bids/bidder x 1.1 hr/bid) at a cost of \$2,101,805 (20,167 hr x \$104.22/hr) for completing Form B.

Regulatory Section in Title 42 of the CFR	Form	# of Respondents	Total # of Responses	Time per Response (hours)	Total Time (hours)	Labor Rate (\$/hr)	Total Cost (\$)	Annualized Time (hours)	Annualized Costs (\$)
Attestation (§414.414(d))	Form A	833.33	833.33	0.1 hr/bid	83	104.22	8,650	83	8,650
Submission of Covered Documents (§414.414(d))	Form A	1,500	500	(5.25) hr/bid	(2,625)	104.22	(820,733)	(2,625)	(273,578)
<i>Subtotal: Form A</i>		2,333	1,333	<i>varies</i>	(2,542)	104.22	(812,083)	(2,542)	(264,928)
Adjustments to Single Payment Amounts (§ 414.408(b))	Form B	1,000	1,000	0.4 hr/bid	(14,500)	104.22	(1,511,190)	(4,833)	(503,730)
Capacity Estimates (§ 414.414(h))	Form B	1,000	1,000	1.5 hr/bid	(75,000)	104.22	(7,816,500)	(25,000)	(2,605,500)
Develop Bid Amount (§ 414.402)	Form B	833.33	18,333	1.1 hr/bid	20,167	104.22	6,308,228	20,167	2,101,805
<i>Subtotal: Form B</i>		2,833	20,333	<i>varies</i>	(69,333)	104.22	(3,019,462)	(9,666)	1,007,422
TOTAL	n/a	2,333 (1,500 + 833)	21,666	Varies	(71,875)	104.22	(3,831,545)	(12,208)	(1,272,350)

Burden Reconciliation

Form	No. Respondents	Annual Responses	Annual Time (hr)s	Annual Cost (\$)
FORM A				
Form A (Active)	500	500	4,175	435,119
CMS-1828-P	2,333	1,333	(2,542)	(264,928)
<i>Subtotal</i>	2,833	1,833	1,633	170,191
FORM B				

Form B (Active)	500	17,500	52,500	5,471,550
CMS-1828-P	2,833	20,333	(9,666)	1,007,425
<i>Subtotal</i>	3,333	37,833	42,834	6,478,975
Total	6,166	39,666	44,467	6,649,166

16. Publication/Tabulation Dates

The make, manufacturer, and model data collected from contract suppliers completing Form B will be used in populating and updating the Supplier Directory on Medicare.gov.

17. Expiration Date

CMS will display the expiration date at the bottom of Form A and Form B upon approval from OMB.

18. Certification Statement

There are no exceptions to the certification statements.

B. Collection of Information Employing Statistical Methods

This collection of information does not employ statistical methods.