

## V. Section 6410 and MIPPA: Adjustments to the Metropolitan Statistical Areas (MSA) for Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Competitive Acquisition Program

Both MIPPA and the ACA have provided specific requirements for the MSA selection for round 2 and beyond. Due to their specified requirements, CMS' proposals are outlined for implementing the requirements regarding the MSA selection according to both MIPPA and the ACA.

CMS proposes the subdivision of Metropolitan Statistical Areas (MSAs) with populations greater than 8,000,000 into separate CBAs under Round 2 of DMEPOS CBP. They propose to exclude certain areas from round 2 of the competitive bidding program, such as: rural areas; MSAs not selected under Round 1 or 2 with a population of less than 250,000; and certain areas with low population density within a selected MSA. Also, CMS proposes to implement the requirement to expand Round 2 of the program by adding 21 of the largest MSAs to the original 70 previously selected.

### 2. Subdividing large MSAs under Round 2

The Secretary has the authority to subdivide MSAs with populations of at least 8,000,000 into separate areas for competitive bidding purposes. CMS has identified three MSAs which could be subdivided: Chicago-Naperville-Joliet, Illinois-Indiana-Wisconsin MSA; Los Angeles-Long Beach-Santa Ana, California MSA; and New York-Northern New Jersey-Long Island, New York-New Jersey-Pennsylvania MSA. CMS is proposing to divide these MSAs into separate CBAs because this approach could provide more manageable CBAs for contract suppliers. This may also allow more of the small suppliers to be considered for participation in the program.

Certain factors, such as the geographic, social, and economic integration of each of the MSAs were acknowledged when considering whether to propose subdividing the MSAs with populations of at least 8,000,000. CMS also uses these factors to determine whether or not to subdivide an MSA into separate CBAs. Once the decision is made to subdivide the MSA, they use the factors previously mentioned to determine how to subdivide the MSA.

CMS found that counties clearly outline areas within an MSA, so they are proposing to subdivide the MSAs at a county level. Which means counties will be used to subdivide CBAs.

Using the factors identified, CMS could subdivide the Chicago-Naperville-Joliet, IL-IN-WI MSA into four separate CBAs: Indiana-Chicago Metro CBA; South-West-Chicago-Metro CBA; Central-Chicago Metro CBA; and Northern-Chicago Metro CBA.







Prior to the required change that the competition for Round 2 of the program occur in 91 of the largest MSAs in 2011, Round 2 was to include 70 MSAs. The 21 MSAs to be included in Round 2 are the next 21 largest metropolitan statistical areas. The additional 21 MSAs added to Round 2 are shown in Table 43.

**TABLE 43: Additional 21 MSAs Added to Round 2**

<b>21 Additional MSAs</b>	<b>2009 Total Population</b>
Philadelphia-Camden-Wilmington, PA-NJ-DE-MD	5,968,252
Washington-Arlington-Alexandria, DC-VA-MD-WV	5,476,241
Boston-Cambridge-Quincy, MA-NH	4,588,680
Phoenix-Mesa-Scottsdale, AZ	4,364,094
Seattle-Tacoma-Bellevue, WA	3,407,848
St. Louis, MO-IL	2,828,990
Baltimore-Towson, MD	2,690,886
Portland-Vancouver-Beaverton, OR-WA	2,241,841
Providence-New Bedford-Fall River, RI-MA	1,600,642
Buffalo-Niagara Falls, NY	1,123,804
Rochester, NY	1,035,566
Tucson, AZ	1,020,200
Honolulu, HI	907,574
Albany-Schenectady-Troy, NY	857,592
Worcester, MA	803,701
Oxnard-Thousand Oaks-Ventura, CA	802,983
Springfield, MA	698,903
Bradenton-Sarasota-Venice, FL	688,126
Poughkeepsie-Newburgh-Middletown, NY	677,094
Stockton, CA	674,860
Boise City-Nampa, ID	606,376

## G. DMEPOS Provision

### 1. Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP)

#### a. Legislative and Regulatory History of DMEPOS CBP

Medicare will pay for most DMEPOS furnished after January 1, 1989, proceeding fee schedule methodologies. The Medicare payment for these items is equal to 80 percent of the lesser of the actual charge for the item or the fee schedule amount for the item. The following separate payment categories of durable medical equipment (DME) were promoted:

- Inexpensive or other routinely purchased items
- Items requiring frequent and substantial servicing
- Customized items
- Oxygen and oxygen equipment
- Other items of DME

Blood glucose testing strips, or diabetic testing strips, are covered under the Medicare DME benefit as well as other supplies that are necessary for the effective use of DME.

Under the DMEPOS CBP, payment amounts for selected DMEPOS items and services furnished to beneficiaries in competitive bidding areas (CBAs) are set by Medicare. These payment amounts are based on bids submitted by qualified suppliers and accepted by Medicare. The new payment amounts, known as single payment amounts (SPA), replace the fee schedule payment methodology for competitively bid items. Unless the total amounts to be paid to contractors in a CBA are expected to be less than the total amounts that would otherwise be paid under the fee schedule, the awarding of contracts to any entity are prohibited. The program also ensures beneficiary access to quality DMEPOS items and services.

The program was implemented by conducting the first round of competition in 10 of the largest MSAs in 2007. Competition was limited to DMEPOS items and services in 10 selected product categories during the first round of the program. The bidding window opened May 15, 2007. It was then extended to allow bidders enough time to prepare and submit their bids. After the bids were submitted, each submission was evaluated and contracts were awarded based on the requirements. Contracts were awarded to qualified suppliers, so following the bid evaluation process, 329 contracts were awarded.

Beginning July 1, 2008, the DMEPOS CBP was effective. Medicare coverage for competitively bid DMEPOS items and services furnished in the first 10 CBAs was limited to items and services furnished by contract and grandfathered suppliers of oxygen and oxygen equipment and rented DME. Payment to these suppliers was based on the SPA, determined under the competitive bidding regulations.

The MIPPA was enacted on July 15, 2008. It delayed competition under the program as well as terminated the competitive bidding contracts effective June 30, 2008. The MIPPA also prohibited payment based on the contracts.

The MIPPA also required the Secretary to conduct a second competition to select suppliers for Round 1 in 2009 ("Round 1 Rebid"), which includes the same items and services and is to be conducted in the same areas as the 2007 Round 1 competition. During the Round 1 Rebid there were certain limited exceptions, such as: the

exclusion of the product category of negative pressure wound therapy (NPWT) items and services; the San Juan, Puerto Rico CBA from the Round 1 Rebid; and group 3 complex rehabilitative wheelchairs. The MIPPA delayed competition for Round 2 of the DMEPOS CBP from 2009 to 2011. The MIPPA specifically addresses the phase in of a competition for national mail order items and services by specifying that such competitions may be phased in after 2010.

b. Implementation of a National Mail Order DMEPOS Competitive Bidding Program (CBP) for Diabetic Testing Supplies

CMS conducted competition in the Round 1 Rebid for mail order diabetic testing supplies in 9 of the 10 CBAs selected in Round 1. A mail order contract supplier is defined as items ordered via phone, email, Internet, or mail and delivered to a beneficiary's residence by common carriers such as; U.S. Postal Service, Federal Express, United Parcel Service, or other shipping or courier service companies. However, this did not include items obtained by beneficiaries from local retail storefronts.

In order for Medicare to pay for diabetic testing supplies obtained via mail order by Medicare beneficiaries, they must purchase these supplies from a mail order contract supplier. Beneficiaries who do not obtain their testing supplies through mail order may purchase these products from any enrolled Medicare supplier. Medicare payment for these items will be at the fee schedule amount. The home blood glucose monitor (diabetic testing equipment) itself is not included in the Round 1 DMEPOS CBP for mail order diabetic supplies, which allows the beneficiary to go to any enrolled supplier to obtain the monitor that best meets their medical needs. The supplier of the glucose monitor is responsible for training the beneficiary on how to use the monitor, for answering follow up questions and providing all services required by the DMEPOS quality standards and supplier standards. The beneficiary has the choice of obtaining the replacement diabetic testing supplies that work with their purchased monitoring system from any local, non-mail order supplier or from a mail order supplier whose contract requires them to ship the replacement diabetic supplies directly to the beneficiary's home.

(1) National Mail Order DMEPOS CBP

Using mail delivery for items that can be provided directly to the beneficiary's home was recommended by the Government Accountability Office (GAO). The beneficiary's choice to go to any local pharmacy to obtain their diabetic supplies, and other items that can be provided by local pharmacies, is maintained through the creation of a competition for items furnished on a mail order basis. This competition would excuse local pharmacies from competing with national mail order suppliers.

(2) DMEPOS CBP for National Mail Order Diabetic Supplies

Published in the January 16, 2009 Federal Register was an interim final rule (IFC) implementing certain changes to the DMEPOS CBP. Certain MIPPA provisions that delayed implementation of Round 1 of the program were implemented by the rule, as well as, requiring CMS to conduct a second Round 1 competition in 2009, and authorized changes for both the Round 1 Rebid and the rounds to follow.

(3) Overview of Proposed Rule

CMS is proposing to implement a national mail order DMEPOS CBP for diabetic testing supplies. Under this national mail order DMEPOS CBP is where we would award contracts to suppliers to furnish these items across the nation to beneficiaries. The beneficiaries they would be providing with these items would have elected to have replacement diabetic testing supplies delivered to their residence. Suppliers would be required to submit bids in order to participate in any DMEPOS CBP implemented for the furnishing of mail order items if they wish to provide these items to Medicare beneficiaries through mail order. The payment

for mail order diabetic supplies would be based on the SPA, which is determined from the bids submitted and accepted for the furnishing of diabetic testing supplies by mail order throughout the CBA.

CMS is also proposing a revised definition of “mail order” so there would be a clear distinction between mail order items and non-mail order items, which would apply to all future competitions for mail order items and services. Suppliers will be required to show that their bid covers at least 50 percent of all types of diabetic testing strips if they bid in competitions to provide diabetic testing strips after the Round 1 Rebid. The Secretary may reject that bid if they supplier is unable to satisfy this requirement. CMS is proposing a new term in contracts of mail order suppliers of diabetic testing supplies following the Round 1 Rebid that would prohibit suppliers from influencing beneficiaries to change their brand of glucose monitor and test strips.

#### (4) Future Competitions for Diabetic Testing Supplies

The establishment of DMEPOS CBP for items including diabetic testing supplies has been authorized. The phase in of items and services under these programs begins with the highest cost and highest volume items and services or those items and services that are determined to have the largest savings potential. Mail order diabetic testing supplies are high volume items because they account for approximately one billion dollars in allowed charges per year. As long as certain refinements are made to the program to address concerns about the mail order/non-mail order division, the implementation of a national mail order DMEPOS CBP for diabetic testing supplies is believed to be the best option for meeting the requirements of the statute referenced above.

CMS is proposing to add a definition of “National mail order DMEPOS CBP” as a program where contracts are awarded to suppliers for furnishing of mail order items across the nation. CMS believes that implementing a national competitive bidding program for diabetic supplies would maintain the beneficiary’s choice to purchase testing supplies from any local pharmacy enrolled as a Medicare supplier that provides diabetic supplies.

Other alternatives for establishing DMEPOS CBP for diabetic testing supplies were considered. These alternatives include:

- A national competition among all types of suppliers for all replacement diabetic supplies. With this alternative, beneficiaries would receive their replacement diabetic supplies from contract suppliers who are responsible for providing diabetic supplies throughout the nation. Suppliers may furnish these supplies using any method of delivery as long as the supplies are delivered on a timely basis.
- Competitions in regional CBAs among all types of suppliers for all replacement diabetic supplies. With this alternative, beneficiaries would receive their replacement diabetic supplies from contract suppliers who will provide diabetic supplies throughout a designated region of the country. Suppliers may use any method of delivery to a beneficiary’s home to provide these supplies, as long as the supplies are delivered on a timely basis.
- Competitions in local CBAs among all types of suppliers for all replacement diabetic supplies. With this alternative, beneficiaries would receive their replacement diabetic supplies from contract suppliers who will provide diabetic supplies throughout the local area. Suppliers may use any method of delivery to provide these supplies to a beneficiary’s home as long as the supplies are delivered on a timely basis.

The first option to bid on a national basis for all diabetic supplies might generate more savings than a national competition for diabetic supplies provided on a mail order basis only. This option, as well as the other two options, would likely eliminate the beneficiary's choice to obtain replacement diabetic supplies on a non-mail order basis from any enrolled supplier where a licensed pharmacist is on hand. The alternatives of regional or local competitions are not likely to result in savings at or above the level that can be generated from a national competition for mail order supplies. Due to these issues, CMS is not proposing any of these alternatives at this time.

For the purpose of awarding contracts to suppliers who will provide replacement diabetic testing supplies across the nation, CMS is proposing to create a national mail order DMEPOS CBP with competitions taking place after 2010.

(5) Definition of Mail Order Item

CMS is proposing to define "mail order item" as well as "non-mail order item". "Mail order item" is defined as any item shipped or delivered to the beneficiary's home, regardless of the method of delivery, while "non-mail order item" is defined as any item that a beneficiary or caregiver can pick up in person at a local pharmacy or supplier storefront.

For Round 1 and the Round 1 Rebid of the DMEPOS CBP, mail order contract supplier was defined as a contract supplier that furnishes items through the mail. Mail order in program instructions was further defined as items ordered by telephone, e-mail, internet or mail and delivered to the beneficiary's residence by common carriers such as; U.S. Postal Service, Federal Express, United Parcel Service. This does not include items obtained by beneficiaries from local storefronts.

Due to the specific requirement of MIPPA to rebid Round 1 in 2009, this proposed definition of mail order item would not apply to the Round 1 competition.

(6) Special Rule in Case of Competition for Diabetic Testing Strips

A supplier must show that their bid to furnish diabetic testing strips covers the furnishing of a sufficient number of different types of diabetic testing strip products that account for at least 50 percent of all such types of products on the market. Since test strips are not manufactured to allow use of different brands of test strips in different brands of monitors, when a beneficiary needs replacement test strips, they must obtain the specific brand of test strip products that work with their brand and model of blood glucose monitor. It is the supplier's responsibility to ensure that the specific brand and model of test strips is provided to the beneficiary so that they match with their purchased monitor.

If awarded a contract, bidding suppliers are required to provide information on the products they plan to furnish under the DMEPOS CBP. CMS proposes to use this information to educate suppliers on meeting the requirements of this special rule.

The 50 percent threshold would ensure that beneficiaries have access to mail order delivery of the top-selling diabetic test strip products. Since the contract supplier would not be able to carry a limited variety of products and switch beneficiaries to those products, CMS is proposing an "anti-switching provision" that should anticipate the need to establish a threshold of greater than 50 percent.

CMS is proposing to define "diabetic testing strip products" as a specific brand and model of test strip, as that is the best way to distinguish among different products. The special rule applies to all competitions for diabetic testing strips after the first round of DMEPOS CBP, which means it would be applies to non-mail order competitions and/or local competitions conducted for diabetic testing strips after Round 1.

(7) Anti-Switching Rule in Case of Competition for Diabetic Test Strips

It is not believed that the 50 percent rule can effectively be applied if an anti-switching rule to prevent suppliers from influencing beneficiaries to switch monitors is not established. Suppliers may offer 50 percent of the brands on the market but continue to switch beneficiaries to the least expensive brands if the anti-switching rule is not applied.

CMS is proposing to prohibit suppliers awarded contracts for diabetic testing supplies from influencing the beneficiary to switch the brand of glucose monitor and testing supplies they are currently using. They are proposing that contract suppliers continue to provide the brand of testing supplies that work with the monitor currently in use by the beneficiary. The supplier's responsibility is to provide the brand of testing supplies that work with the blood glucose monitor product that the beneficiary and/or clinician selects. The supplier should not influence the beneficiary to use specific brands. The beneficiary may ask for assistance from the supplier to select a monitor if the beneficiary needs a blood glucose monitor for the first time, or needs to replace their existing one, and neither the beneficiary nor their physician has determined which brand or type of monitor. The supplier would then have to show the beneficiary the full range of products.

c. Off-the-Shelf (OTS) Orthotics Exemption

The April 10, 2007 final rule sets forth several exceptions to the DMEPOS CBP, which are applicable to providers, physicians, and treating practitioners that furnish certain DMEPOS items under Medicare Part B. The items exempted are limited to crutches, canes, walkers, folding manual wheelchairs, blood glucose monitors, and infusion pumps that are DME. The items must be furnished by a physician or treating practitioner to his or her own patients for the exemptions to apply. In order for these items to be billed, a billing number is assigned to the physician, the treating practitioner, or a group practice to which the physician or treating practitioner has given the right to receive Medicare payment.

The exemptions from the DMEPOS CBP are expanded for certain OTS orthotics to physicians or other practitioners if furnished to their own patients as part of their professional service. MIPPA also expanded the exemption from the program to hospitals for certain OTS orthotics, crutches, canes walkers, folding manual wheelchairs, blood glucose monitors, and infusion pumps if these items are furnished to the hospital's own patients during an admission or on the date of discharge.

d. Grandfathering Rules Resulting in Additional Payments to Contract Suppliers under the DMEPOS Competitive Bidding Program (CBP)

The Secretary must establish a "grandfathering" process in case of rented DME and oxygen and oxygen equipment. If a beneficiary was renting DME items or receiving oxygen and oxygen equipment prior to the DMEPOS CBP from a supplier who did not win a contract, the beneficiary can continue to rent the equipment from that noncontract supplier if that supplier chooses to become a grandfathered supplier. The contract supplier will receive a minimum of 10 monthly payments for taking over the furnishing of oxygen and oxygen equipment when the beneficiary decides to receive their oxygen equipment and supplies from a contract supplier instead of a grandfathered supplier.

The supplier was authorized to transfer title to the equipment to the beneficiary after both the 13-month cap for capped rental items and the 36-month cap for oxygen equipment. Suppliers now get the equipment back when the beneficiary no longer needs it, as it states in the revised oxygen payment provisions. Also, the beneficiary had the option to access standard power wheelchairs on a lump sum purchase basis. Therefore, those items generally would not be affected by the grandfather rules. However, the lump sum purchase option

for standard power wheelchairs is eliminated. This applies to items furnished under the DMEPOS CBP beginning with Round 2.

The grandfathering rules may place a financial burden on beneficiaries who are near the end of the 13 or 36-month rental cap periods. The beneficiary will be required to switch to a contract supplier in order for Medicare to continue to pay for the furnishing of the rental equipment if their existing supplier chooses not to be a grandfathered supplier. In these cases, the beneficiary will be responsible for additional co-insurance amounts. At the beginning of a DMEPOS CBP, some beneficiaries who have already made 12 of their 13 coinsurance payments for a capped rental item could make as many as 12 additional copayments as a result of restarting the capped rental period when they switch from a noncontract supplier to a contract supplier.

#### e. Appeals Process

According to the DMEPOS CBP final rule issued on April 10, 2007, “any deviation from contract requirements, including a failure to comply with governmental agency or licensing organization requirements, constitutes a breach of contract.” If it is determined that a contract supplier’s actions form a breach of contract, one or more of the following actions will take place:

- Require the contract supplier to submit a corrective action plan;
- Suspend the contract supplier’s contract;
- Terminate the contract;
- Preclude the contract supplier from participating in the DMEPOS CBP;
- Revoke the supplier number of the contract supplier; or
- Avail itself of other remedies allowed by the statute.

#### Proposed Appeals Process

Proposed in this rule, policies and procedures relating to our determinations of a breach of contract and the appeals process for contract suppliers that are considered to be in breach of contract would be set forth.

Due to the impact termination has on a contract supplier it may be beneficial for contract suppliers to have access to an appeal process in the chance that their contract(s) may be terminated due to a breach of contract. CMS chose to propose a simplified process that would not disrupt the program by having suppliers going in and out of the program, which is why CMS proposes a process for review and reconsideration before the contract is actually terminated. Since the supplier would generally not be terminated until a final decision is made, the supplier would be protected. Suppliers may also be allowed to submit a corrective action plan (CAP) depending upon the nature of the breach, which could be beneficial to some suppliers.

#### (1) Purpose and Definitions:

CMS is proposing to amend the definitions of the following terms:

- Affected party, which means a contract supplier that has been notified that their DMEPOS CBP contract would be terminated for a breach of contract.
- Breach of contract, which means any deviation from contract requirements, including a failure to comply with a governmental agency or licensing organization requirements.

- Corrective Action Plan (CAP), which means a contract supplier's written document with supporting information that describes the actions the contract supplier would take within a specified timeframe to remedy the breach of contract.
- Competitive Bidding Implementation Contractor (CBIC) Hearing Officer (HO), which means an individual, who was not involved with the CBIC recommendation to terminate a DMEPOS CBP contract, who is designated by CMS to review and make an unbiased and independent determination from the CBIC's recommendation to terminate a DMEPOS CBP contract.
- Parties to the Hearing, which means the DMEPOS contract supplier and CMS.

## (2) Applicability

The proposed appeals process would allow contract suppliers the opportunity for a review of the following:

- A CMS determination under §414.422(g)(1) that the contract supplier breached its contract entered into as part of the DMEPOS CBP; and
- Certain agency actions taken under §414.422(g)(2).

The proposed appeals process would be in addition to existing CMS regulations regarding other appeals mechanisms, it would not replace them.

When a termination decision is issued under the CMS proposal, it would be final and binding unless a postponement of the termination decision is allowed.

## (3) Contract Termination

When the supplier has received a notice that CMS has determined they are in breach of contract and their contract is subject to termination, the appeals process applies. A contract may be terminated for any violation of the terms of the contract. Examples of violations include, but are not limited to, the following situations where the contract supplier:

- Has committed or participated in false, fraudulent, or abusive activities affecting the Medicare program, including the submission of false or fraudulent data or claims;
- Experiences financial difficulties so that they are unable to effectively provide the necessary services to a Medicare beneficiary; or
- Fails to meet the non-discrimination policy and provides different items to beneficiaries located in a competitive bidding area (CBA) that it provides to its non-Medicare beneficiaries

## (4) Notice of Termination

Before sending a recommendation to CMS that the supplier's contract be terminated, the CBIC would work with suppliers to resolve performance deficiencies informally under its DMEPOS CBP contract. CMS would review the CBIC's recommendation to terminate the supplier's contract if the CBIC cannot informally resolve the supplier's deficiencies and recommends that the contract be terminated. The termination process would begin with a notice of termination being sent to the supplier if CMS finds that a breach has occurred.

The notice would explain all actions CMS plans to take in response to the supplier's breach and if the supplier decides to appeal any of these decisions, the supplier would submit an appeal in response to the notice. The notice would signify that the contract supplier has been found to be in breach of contract and

that, within 45 calendar days of the date of the notification of termination, the supplier's contract would be terminated. The notification will be mailed on the date that it is signed.

The notice is required to include, at a minimum, the following information which would provide the supplier with the basis for CMS's action, as well as their options in responding to the decision:

- The reasons for the termination in sufficient detail to allow the contract supplier to understand the nature of its breach of contract;
- Depending on the nature of the breach, whether the supplier may be allowed to submit a CAP in lieu of requesting a hearing by the HO;
- The right to request a hearing by the HO;
- The address to which the written request for a hearing must be mailed;
- The address to which the CAP must be mailed; and
- The effective date of the termination of the contract, if a CAP is not submitted or if a request for a hearing has not been filed timely.

Any additional penalties that may result from termination, such as, not being eligible to bid in future rounds of competitive bidding, are required to be discussed in the notice.

#### (5) Corrective Action Plan

A process by which a contract supplier may be able to submit a CAP to address the breach of contract is also being proposed by CMS. CMS proposes that the notice to the supplier would state whether a contract supplier would be allowed to provide a written CAP instead of submitting a request for a hearing by a HO.

Related to the CAP, CMS is proposing timelines for the instances where the supplier decides to submit a CAP. The CAP must be received by the CBIC within 30 calendar days from the date on the notice of termination, if the supplier decides to submit a CAP. The termination determination would be postponed while the CAP is being evaluated.

The CAP would be required to indicate that the contract supplier has a plan to fix all of the deficiencies identified in the notice of termination. The supplier must also specify the timeframes for which they will be correcting these deficiencies. The CAP will be reviewed by the CBIC to ensure that the supplier would be taking suitable measures in a timely manner, which is determined based on the type of deficiency that is being corrected, to fix the breach of contract. CMS expects most deficiencies to be corrected within 90 days or less.

Contract suppliers will receive guidance from the CBIC as a part of the review process regarding the type of documentation that the CAP and the follow up report must provide to substantiate that the deficiencies have been corrected. The guidance provided by the CBIC will be in accordance with CMS instructions. CMS may discuss the CAP with the supplier to determine whether the CAP would be considered acceptable and the CBIC will allow a supplier to make revisions to its CAP during the review process. Within 45 calendar days the contract supplier's contract would be terminated if it does not submit an acceptable CAP during the review process. If the submitted CAP is not acceptable, the supplier would receive a new notice stating that their CAP is not acceptable or has not been implemented consistent with the supplier's original submission. A new notice would be sent to the supplier of the termination of the contract and provide notice that the supplier may request a hearing on this termination if they fail to develop and implement an approved CAP. When an acceptable CAP has been completed a follow-up report must be provided by the supplier within 5 days of the agreed upon date for the completion of the CAP to verify that all deficiencies

identified in the CAP have been corrected according to the time frames specified in the CAP and approved by the CMS.

(6) Right to Request a Hearing by the CBIC Hearing Officer (HO)

If a contract supplier has received a notice stating they are considered in breach of contract, the supplier has the right to request a hearing before a HO who is designated by CMS to review and to make an unbiased recommendation of whether to terminate the contract. The notice sent to the contract supplier would identify the location to which a request for hearing must be sent. This process is a reconsideration of the original decision, so it is important that an individual not involved in making the original recommendation conduct the reconsideration of the initial decision.

Any evidence to support the appeal should be included in the written request; however, the HO is not required to allow evidence submitted in addition to the evidence submitted with the written request. The CBIC should receive the hearing request within 30 calendar days from the date of the termination letter. If the contract supplier does not request a hearing within the 30 calendar days given, the supplier's contract will be terminated at the effective date of termination identified in the notice to the supplier. There would be no extensions to this 30-day timeframe.

Because an authorized official of the company signed the contract, the request for hearing is required to be filed by a supplier's authorized official. This ensures the validity of the request. However, a supplier may appoint someone other than the authorized official to be a representative for them at the hearing.

(7) Scheduling the Hearing

CMS proposes that the HO would contact the parties to schedule a hearing within 30 calendar days from the receipt of a supplier's timely hearing request. The date of the contract termination would be postponed if there was a request for a hearing. The contract supplier may ask for the hearing to be held in person or by telephone in the hearing request. In the case of a hearing request, the HO would send a notice to the parties associated with the hearing 30 days prior to the date of the hearing indicating the time and place for the hearing. If the HO changes the time and place for the hearing on his or her own motion, or at the request of a party, the HO must provide the parties to the hearing a 30 day notice of the change.

The HO's notice scheduling the hearing must, at minimum, provide the following information:

- Date, time, and location of the scheduled hearing;
- Description of the hearing procedure;
- Issues to be resolved;
- Requirement that the contract supplier bears the burden of proof to demonstrate that it is not in breach of contract; and
- Provide an opportunity for the supplier to submit evidence to support its appeal.

(8) Burden of Proof

The supplier's supporting evidence must be submitted, along with its request for a hearing, within 30 calendar days from the date identified on the notice of termination and received by the HO. The contract supplier would present the reason for its disagreement with the termination notice and would have the burden of proof to present to the HO with supporting evidence that it is not in breach of its contract. The HO will share all evidence submitted, from both the supplier and CMS, with all affected parties within 15 days prior to the scheduled date of the hearing.

#### (9) Role of the Hearing Officer (HO)

The HO is required to conduct a thorough and independent review considering all information and documentation relevant to the hearing. The HO is responsible for the following:

- Sharing all evidence submitted, both from supplier and CMS, in preparation for the hearing with all affected parties within 15 days prior to the scheduled date of the hearing.
- Conducting the hearing and deciding the order in which the evidence and the arguments of the parties would be presented.
- Determining the rules on admissibility of the evidence.
- Examining the witnesses, in addition to the examinations conducted by CMS and the contract supplier.
- Determining the rules for requesting documents and other evidence from other parties.
- Ensuring a complete recording of the hearing is available and provided to all parties to the hearing and the CBIC.
- Preparing a file of the record of the hearing which includes all evidence submitted as well as any relevant documents identified by the HO and considered as part of the hearing.
- Complying with all applicable provisions of 42 USC Title 18 and related provisions of the Act, the applicable regulations issued by the Secretary, and manual instructions issued by CMS.

The HO is responsible for making a written recommendation to CMS within 30 days of the close of the hearing based on the information presented and submitted. If the HO needs and extension due to complexity of the matter or heavy work load the HO may request an extension from CMS. The HO would submit the recommendation to CMS for its determination.

#### (10) CMS's Final Determination

The HO's recommendation is submitted to CMS and the agency would make the final determination of whether the supplier's contract would be terminated. CMS's determination would be based on the record of the hearing, evidence, and documents considered by the HO. CMS's decision would be made within 30 days of the receipt of the HO's recommendation, and if their decision is to terminate the contract, the supplier would be notified by mail of the effective date of termination. CMS's decision to terminate the contract is final and binding.

#### (11) Effective Date of the Contract Termination

The termination date identified on the noticed would be delayed if a supplier submitted a CAP or requested a hearing. The only exception is when a supplier has been excluded, debarred or convicted of a health care related crime, in which the contract would then be terminated immediately. The effective date of a final termination would be determined as follows for those who do not meet these exceptions:

- The termination of a supplier's DMEPOS CBP contract is effective on the date specified in the initial notice of termination, which will be 45 days from the date of the notice, unless the supplier request a hearing with the HO or the supplier submits an acceptable CAP.
- After reviewing the HO recommendation, if we terminate a supplier's contract the effective date of the termination would be the date specified in the post-hearing notice sent to the supplier indicating CMS's final determination to terminate the contract.

#### (12) Effect of Contract Termination

The contract supplier is no longer a DMEPOS CBP contract supplier for any DMEPOS CBP product category for which it was awarded a contract once a supplier's contract is terminated for breach of contract. Since there is only one contract that includes all CBAs and product categories for which the supplier was awarded a contract, the termination applies to all areas and product categories.

The beneficiaries within the CBA where a supplier has been terminated will be affected. The terminated suppliers must notify all beneficiaries within the CBA who are receiving rented competitively bid items of the termination of their contract status within 5 days of the receipt of the contract supplier's final notice of termination. Beneficiaries will need to make arrangements to receive equipment and supplies through other contract suppliers, which means the notice should inform beneficiaries that they would have to choose a new contract supplier to provide their DMEPOS items in order for Medicare to pay for them. CMS is also proposing that rental items may not be picked up from the beneficiary's home until after the last day of the rental month in which the supplier has already received payment for.