



## **Summary of DME Issues in Physician Fee Schedule Proposed Rule June 29, 2010**

The Centers for Medicare and Medicaid Services (CMS) on June 25, 2010, issued proposed changes to the competitive bidding program for durable medical equipment, orthotics, prosthetics, and supplies (DMEPOS) and oxygen payment policy in the proposed rule: *Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011* [CMS-1503-P]. The rule also outlines the payment schedule related to the elimination of the first-month purchase option for standard power wheelchairs. The rule is expected to be published in the *Federal Register* on July 13, 2010. Comments are due 60 days after publication of the rule. The following is a summary of the key issues in the proposed rule that impact the DME industry.

### **Proposed Changes to “Grandfathering”**

The proposed rule solicits comments related to the number of payments that a contract provider under the competitive bidding program can receive for capped rental items and oxygen equipment in the event that non-contract providers choose not to “grandfather” their existing patients. Currently, if a beneficiary chooses to use a contract provider under the bidding program rather than a “grandfathered” provider for oxygen equipment, the new provider is eligible to receive a minimum of 10 monthly rental payments. If a beneficiary chooses to switch from a “grandfathered” provider to a contract provider for a capped rental item, the 13-month capped rental period restarts for the contract provider.

In the proposed rule, CMS notes that several payment policies have changed since the Agency developed the payment policies for patients who switch from a “grandfathered” provider to a contract provider: the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) repealed the title transfer requirement for oxygen equipment, and the Patient Protection and Affordable Care Act (ACA) eliminated the first-month purchase option for standard power wheelchairs. According to CMS, most contract suppliers are likely to choose to become “grandfathered” providers, so the additional months of payment will not impact a significant amount of beneficiaries. However, the Agency believes that the additional payments under the current grandfathering rules are burdensome to beneficiaries who are nearing the end of the 13- or 36-month rental periods and choose to switch from a non-contract provider to a contract provider. Therefore, CMS is requesting comments on whether it is appropriate to reduce the number of additional rental payments that a contract provider can receive in these situations.

## **Proposed Changes to Oxygen Payment Rules**

CMS' rule proposes changes to payment rules for oxygen and oxygen equipment for beneficiaries who have not reached the 36-month rental cap. Under the proposed changes, the oxygen provider who receives payment in the 18<sup>th</sup> rental month or later must continue to furnish the equipment for the period of medical necessity through the useful lifetime of the equipment, which CMS has defined as five years. If the beneficiary relocates outside of the provider's normal service area after month 18 of continuous payment, the provider would be required to arrange for furnishing the oxygen equipment with another provider for the five-year useful lifetime of the equipment.

Currently, CMS requires that the supplier who provided oxygen equipment to the beneficiary in month 36 be responsible for providing or arranging for the provision oxygen equipment and service to the patient through the period of medical necessity through the end of the equipment's useful lifetime regardless of the beneficiary's location. The proposed changes in the rule would change this requirement from month 36 to month 18. For beneficiaries who relocate prior to the 18<sup>th</sup> month, there is no requirement that the provider continue to furnish oxygen equipment to a beneficiary who relocates outside of the provider's service area.

CMS states that its reason for proposing the change to 18 months is because the Agency has been made aware of many reports of patients relocating prior to the 36<sup>th</sup> month of rental who are experiencing difficulties finding a new oxygen provider.

## **Proposed Provisions Impacting Round Two of Competitive Bidding**

### **Subdividing Large MSAs**

MIPPA gave CMS exclusive authority to subdivide metropolitan statistical areas (MSAs) with a total population of more than 8,000,000 into separate areas for the purposes of conducting competitive bidding. CMS proposes to use its authority to subdivide these large MSAs. The following MSAs can be subdivided based on this definition:

- (1) Chicago-Naperville-Joliet, Illinois-Indiana-Wisconsin (IL-IN-WI) -- population 9,569,624;
- (2) Los Angeles-Long Beach-Santa Ana, California (CA) -- population 12,872,808; and
- (3) New York-Northern New Jersey-Long Island, New York-New Jersey-Pennsylvania (NY-NJ-PA) -- population 19,006,798.

In determining how to subdivide each MSA, CMS considered the following factors:

- Geographic size of the MSA and the location of the counties within each MSA compared to neighboring counties;
- The driving distances from north to south and east to west within each MSA and county;
- The total population and the population of FFS Medicare beneficiaries using DMEPOS items subject to competitive bidding;
- The DEMPOS allowed charges for items subject to competitive bidding;
- Comparably sized Round 1 and Round 2 MSAs based on beneficiary counts and allowed charges for competitive bid items;
- The interstate highway infrastructures of the MSAs; and

- The current service patterns of suppliers in each county of the MSA.

CMS is considering the advice of the Program Advisory and Oversight Committee (PAOC) on its proposal for subdividing the three MSAs and is accepting comments from the public. CMS proposes to subdivide large MSAs into the following competitive bidding areas (CBAs) by county:

**Chicago-Naperville-Joliet, IL-IN-WI**

<b>Competitive Bidding Area (CBA)</b>	<b>Counties</b>
Indiana-Chicago Metro	<ul style="list-style-type: none"> <li>• Lake, IN</li> <li>• Jasper, IN</li> <li>• Newton, IN</li> <li>• Porter, IN</li> </ul>
South-West-Chicago Metro	<ul style="list-style-type: none"> <li>• Will, IL</li> <li>• Grundy, IL</li> <li>• DeKalb, IL</li> <li>• Kane, IL</li> </ul>
Central-Chicago Metro	<ul style="list-style-type: none"> <li>• Cook, IL</li> <li>• DuPage, IL</li> </ul>
Northern-Chicago Metro	<ul style="list-style-type: none"> <li>• Lake, IL</li> <li>• McHenry, IL</li> <li>• Kenosha, WI</li> </ul>

**Los Angeles-Long Beach-Santa Ana, CA**

<b>Competitive Bidding Area (CBA)</b>	<b>Counties</b>
Los Angeles County	<ul style="list-style-type: none"> <li>• Los Angeles (excluding the area north of the San Gabriel mountains)</li> </ul>
Orange County	<ul style="list-style-type: none"> <li>• Orange</li> </ul>

**New York-Northern New Jersey-Long Island, NY-NJ-PA**

<b>Competitive Bidding Area (CBA)</b>	<b>Counties</b>
Nassau-Brooklyn-Queens County Metro	<ul style="list-style-type: none"> <li>• Nassau, NY</li> <li>• Kings, NY</li> <li>• Queens, NY</li> </ul>
Suffolk County	<ul style="list-style-type: none"> <li>• Suffolk, NY</li> </ul>
Bronx-Manhattan NY	<ul style="list-style-type: none"> <li>• Bronx, NY</li> <li>• New York, NY</li> </ul>
North-West NY Metro	<ul style="list-style-type: none"> <li>• Hudson, NJ</li> <li>• Bergen, NJ</li> </ul>

	<ul style="list-style-type: none"> <li>• Passaic, NJ</li> <li>• Putnam, NY</li> <li>• Rockland, NY</li> <li>• Essex, NJ</li> <li>• Morris, NJ</li> <li>• Sussex, NJ</li> <li>• Pike, PA</li> <li>• Westchester, NY</li> </ul>
Southern NY Metro	<ul style="list-style-type: none"> <li>• Hunterdon, NJ</li> <li>• Richmond, NY</li> <li>• Union, NJ</li> <li>• Middlesex, NJ</li> <li>• Monmouth, NJ</li> <li>• Ocean, NJ</li> <li>• Somerset, NJ</li> </ul>

**Exclusions of Certain Areas after Round 2 and Prior to 2015**

The rule proposes to exclude certain areas from competition after Round Two and before 2015 as follows:

- Rural Areas;
- Metropolitan Statistical Areas not selected under Round 1 or Round 2 with a population of less than 250,000; and
- Areas with a low population density within urban areas that are not competitive, unless there is a significant national market through mail order for a particular item or service.

**Expansion of Round 2**

Section 6410 of ACA requires that CMS expand Round Two of the DMEPOS bidding program from the 70 MSAs that were announced in 2008 to a total of 91 MSAs. The ACA provision required CMS to select the next 21 areas that were not already subject to bidding in Rounds One and Two as the additional MSAs. Round Two bidding competitions are required to take place in 2011. Based on the 2009 U.S. Census population estimates, CMS proposes the following additional areas:

**Additional 21 MSAs Added to Round 2**

#	Additional MSAs	2009 Total Population
1	Philadelphia-Camden-Wilmington, PA-NJ-DE-MD	5,968,252
2	Washington-Arlington-Alexandria, DC-VA-MD-WV	5,476,241
3	Boston-Cambridge-Quincy, MA-NH	4,588,680
4	Phoenix-Mesa-Scottsdale, AZ	4,364,094
5	Seattle-Tacoma-Bellevue, WA	3,407,848
6	St. Louis, MO-IL	2,828,990
7	Baltimore-Towson, MD	2,690,886
8	Portland-Vancouver-Beaverton, OR-WA	2,241,841

<b>9</b>	Providence-New Bedford-Fall River, RI-MA	1,600,642
<b>10</b>	Buffalo-Niagara Falls, NY	1,123,804
<b>11</b>	Rochester, NY	1,035,566
<b>12</b>	Tucson, AZ	1,020,200
<b>13</b>	Honolulu, HI	907,574
<b>14</b>	Albany-Schenectady-Troy, NY	857,592
<b>15</b>	Worcester, MA	803,701
<b>16</b>	Oxnard-Thousand Oaks-Ventura, CA	802,983
<b>17</b>	Springfield, MA	698,903
<b>18</b>	Bradenton-Sarasota-Venice, FL	688,126
<b>19</b>	Poughkeepsie-Newburgh-Middletown, NY	677,094
<b>20</b>	Stockton, CA	674,860
<b>21</b>	Boise City-Nampa, ID	606,376

**Original MSAs for Round 2**

On January 8, 2008, CMS announced the 70 MSAs that would be subject to bidding in Round Two. The 21 additional MSAs listed above would be added to the 70 below to meet the ACA requirement that Round Two bidding be conducted in 91 areas.

The original 70 MSAs for Round 2 are:

**West**

Albuquerque, NM	Sacramento--Arden-Arcade--Roseville, CA
Bakersfield, CA	Salt Lake City, UT
Colorado Springs, CO	San Diego-Carlsbad-San Marcos, CA
Denver-Aurora, CO	San Francisco-Oakland-Fremont, CA
Fresno, CA	San Jose-Sunnyvale-Santa Clara, CA
Las Vegas-Paradise, NV	Visalia-Porterville, CA
Los Angeles-Long Beach-Santa Ana, CA	

**Midwest**

Akron, OH	Indianapolis-Carmel, IN
Chicago-Naperville-Joliet, IL-IN-WI	Milwaukee-Waukesha-West Allis, WI
Columbus, OH	Minneapolis-St. Paul-Bloomington, MN-WI
Dayton, OH	Omaha-Council Bluffs, NE-IA
Detroit-Warren-Livonia, MI	Toledo, OH
Flint, MI	Wichita, KS
Grand Rapids-Wyoming, MI	Youngstown-Warren-Boardman, OH-PA
Huntington-Ashland, WV-KY-OH	

**South**

Asheville, NC	Augusta-Richmond County, GA-SC
Atlanta-Sandy Springs-Marietta, GA	Austin-Round Rock, TX

Baton Rouge, LA  
Beaumont-Port Arthur, TX  
Birmingham-Hoover, AL  
Cape Coral-Fort Myers, FL  
Charleston-North Charleston, SC  
Chattanooga, TN-GA  
Columbia, SC  
Deltona-Daytona Beach-Ormond Beach, FL  
El Paso, TX  
Greensboro-High Point, NC  
Greenville-Mauldin-Easley, SC  
Houston-Sugar Land-Baytown, TX  
Jackson, MS  
Jacksonville, FL  
Knoxville, TN  
Lakeland, FL  
Little Rock-North Little Rock-Conway, AR

Louisville/Jefferson County, KY-IN  
McAllen-Edinburg-Mission, TX  
Memphis, TN-MS-AR  
Nashville-Davidson--Murfreesboro--  
Franklin, TN  
New Orleans-Metairie-Kenner, LA  
Ocala, FL  
Oklahoma City, OK  
Palm Bay-Melbourne-Titusville, FL  
Raleigh-Cary, NC  
Richmond, VA  
San Antonio, TX  
Tampa-St. Petersburg-Clearwater, FL  
Tulsa, OK  
Virginia Beach-Norfolk-Newport News,  
VA-NC

### **Northeast**

Allentown-Bethlehem-Easton, PA-NJ  
Bridgeport-Stamford-Norwalk, CT  
Hartford-West Hartford-East Hartford, CT  
New Haven-Milford, CT

New York-Northern New Jersey-Long  
Island, NY-NJ-PA  
Scranton--Wilkes-Barre, PA  
Syracuse, NY

### **Rule for Elimination of First-Month Purchase Option for Standard Power Wheelchairs**

The ACA eliminates the first-month purchase option for standard power-driven wheelchairs. CMS will retain the first-month purchase option for Group 2 chairs with power options and Group 3 chairs. This provision:

- Applies to power wheelchairs after January 1, 2011, and,
- Does not apply to payment for items and services that are under competitive bidding contracts prior to January 1, 2011 as part of the Round One Rebid of the competitive bidding program.

As required by the ACA, CMS will adjust the payment schedule for power-driven wheelchairs under the Medicare Part B DMEPOS fee schedule to pay 15 percent (instead of 10 percent) of the purchase price for the first three months under the 13 month rental period and 6 percent (instead of 7.5 percent) for the remaining months. This payment revision:

- Applies to power wheelchairs after January 1, 2011, and,
- Does not apply to payment for items and services that are under competitive bidding contracts prior to January 1, 2011 as part of the Round One Rebid of the competitive bidding program.

## **Proposed Changes for the Implementation of a National Mail-Order DME Competitive Bidding Program for Diabetic Testing Supplies**

Contracts and single payment amounts (SPAs) for the Round One rebid for mail-order diabetic testing supplies are scheduled to be available for beneficiaries in 9 CBAs from January 1, 2011 through December 31, 2012. CMS may implement additional competitions for non-mail-order diabetic testing supplies or diabetic supplies and is reviewing savings associated with beneficiaries using diabetes supplies by way of mail-order or retail pathways. CMS is proposing to implement a national mail-order program for diabetic testing supplies - awarding contracts to suppliers to furnish beneficiaries who elect to have replacement diabetic testing supplies delivered to their residence after 2010. Payment would be based on the single payment amount determined from bids submitted and accepted throughout the national CBA.

### **Proposed Changes for Diabetic Testing Strips (50% rule)**

MIPPA states HME providers are required, after the Round One Rebid, to demonstrate that their bid covers at least 50 percent of all types of diabetic testing strips furnished by HME providers. The volume for the different products may be determined in accordance with data (which may include market based data), recognized by the Secretary. The “50 percent rule” applies to all competitions and/or local competitions conducted for diabetic testing strips after Round One of the competitive bidding program. CMS is requesting comments on whether a threshold higher than 50 percent should be used.

In addition, under MIPPA, the HHS Office of Inspector General (OIG) is mandated to conduct a study before 2011 to generate volume data for types of diabetic test strips products. CMS will be using market-based data for specific brands and models of diabetic test strips to determine the relative market share or volume of the various products on the market that are available to Medicare beneficiaries. This data will not be limited to the data furnished in the OIG report.

CMS is requesting public comments on the following for establishing a competitive bidding program for diabetic testing supplies:

1. A national competition among all types of HME providers, both mail-order and retail, for all replacement diabetic supplies.
2. Competitions in regional CBAs among all types of HME providers, both mail-order and retail, for all replacement diabetic HME providers.
3. Competitions in local CBAs among all types of HME providers, both mail-order and retail, for all replacement diabetic providers.

**AAHomecare Comment:** CMS indicates that its preference is option #1 as they believe it is the option that will least impact access.

### **Proposed Anti-switching Rule Regarding Competition for Diabetic Test Strips**

CMS has proposed an anti-switching rule to prevent HME providers from influencing beneficiaries to switch glucose monitors. Under CMS’s proposal, HME providers will be

prohibited from influencing or incentivizing beneficiaries to change their brand of glucose monitor and test strips. CMS is requesting comments on the “anti-switching rule”.

### **Proposed Changes for Definitions Related to Diabetic Supplies**

CMS is proposing to revise the definition of “mail-order” for a national mail-order program after 2010, that is, a program where contracts are awarded to suppliers for the furnishing of mail-order items across the nation. CMS is also defining a mail-order item to be any item shipped or delivered to the beneficiary’s home, regardless of the method of delivery. For a national mail-order program, after 2010, CMS’ proposed definition of a non-mail-order item is any item that a beneficiary or caregiver picks up in person at a local pharmacy or HME provider storefront. CMS is requesting comments on their proposed definition of mail-order and its impact on future rounds of bidding. CMS is also proposing to define “diabetic testing strip product” as a specific brand and model of test strip.