ever the case that certificates were not available for download in the typical timeframe. We want to ensure that facilities have adequate time to post certificates as required in this circumstance, and that the required timing accommodates the December holidays. Therefore, we proposed that, beginning in CY 2014, facilities must post certificates within fifteen business days of CMS making these certificates available for download from dialysisreports.org in accordance with section 1881(h)(6)(C) of the Act.

The comments we received on these proposals and our response are set forth below.

Comment: Several commenters supported the public-reporting proposal to require facilities to post performance score certificates fifteen business days after they are made available.

Response: We thank the commenters for the support.

For this reason, we are finalizing the public reporting requirements as proposed for the PY 2016 ESRD QIP and for future payment years.

IV. Clarification of the Definition of Routinely Purchased Durable Medical Equipment (DME)

A. Background

1. Background for DME

Title XVIII of the Social Security Act (the Act) governs the administration of the Medicare program. The statute provides coverage for broad categories of benefits, including, but not limited to, inpatient and outpatient hospital care, skilled nursing facility care, home health care, physician services, and DME. "Medical and other health services," which is defined under section 1861(s)(6) of the Act to include DME, is a separate Medicare Part B benefit for which payment is authorized by section 1832 of the Act. In accordance with section 1861(n) of the
Act, the term “durable medical equipment” includes iron lungs, oxygen tents, hospital beds, and wheelchairs used in the beneficiary’s home, including an institution used as his or her home other than an institution that meets the requirements of section 1861(e)(1) or section 1819(a)(1) of the Act.

Section 1834(a) of the Act, as added by section 4062 of the Omnibus Budget Reconciliation Act of 1987 (OBRA 87), Public Law 100-203, sets forth the payment rules for DME furnished on or after January 1, 1989. The Medicare payment amount for a DME item is generally equal to 80 percent of the lesser of the actual charge or the fee schedule amount for the item, less any unmet Part B deductible. The beneficiary’s coinsurance for such items is generally equal to 20 percent of the lesser of the actual charge or the fee schedule amount for the item once the deductible is met. The fee schedule amounts are generally calculated using average allowed charges from a base period and then increased by annual update factors.

Sections 1834(a)(2) through (a)(7) of the Act set forth separate classes of DME and separate payment rules for each class. The six classes of items are: inexpensive and other routinely purchased DME; items requiring frequent and substantial servicing; customized items; oxygen and oxygen equipment; other covered items (other than DME); and other items of DME, also referred to as capped rental items. The class for inexpensive and other routinely purchased DME also includes accessories used in conjunction with nebulizers, aspirators, continuous positive airway pressure devices and respiratory assist devices. Items of DME fall under the class for other items of DME (capped rental items) if they do not meet the definitions established in the statute and regulations for the other classes of DME.

2. Medicare Guidance and Rulemaking Regarding Definition of Routinely Purchased DME
On July 14, 1988, CMS issued a program memorandum containing guidance for carriers to follow in developing a data base that would be used in identifying other routinely purchased DME for the purpose of implementing section 1834(a)(2)(A)(ii) of the Act. For the purpose of identifying routinely purchased items, the carriers were instructed via the program memorandum to “compute the unduplicated count of beneficiaries who purchased the item, by Health Care Financing Administration (HCFA) Common Procedure Coding System (HCPCS) code (now the Healthcare Common Procedure Coding System), and a count of those who only rented the item during the 7/1/86 – 6/30/87 period.” The carriers were instructed to include purchase of new and used items and beneficiaries who purchased an item that was initially rented in the count of beneficiaries who purchased the item. The carriers made determinations regarding whether DME furnished during this period would be rented (non-capped) or purchased based on which payment method was more economical.

In November 1988, CMS revised Part 3 (Claims Process) of the Medicare Carriers Manual (HCFA Pub. 14-3) via transmittal number 1279, by adding section 5102 and detailed instructions for implementation of the fee schedules and payment classes for DME mandated by section 4062 of OBRA 87. The new implementing instructions were effective for services furnished on or after January 1, 1989. Section 5102.1.A.2 indicated that carriers would be provided with a listing of the equipment in the routinely purchased DME category. The initial classifications were implemented on January 1, 1989, in accordance with the program instructions, and included a listing of HCPCS codes for base equipment such as canes and walkers, as well as HCPCS codes for replacement accessories such as cane tips, walker leg extensions, and power wheelchair batteries for use with medically necessary, patient-owned base equipment (canes, walkers, and power wheelchairs). In the case of expensive accessories that
were not routinely purchased during July 1986 through June 1987, such as a wheelchair attachment to convert any wheelchair to one arm drive, these items fell under the listing of HCPCS codes for capped rental items. Medicare payment for DME extends to payment for replacement of essential accessories used with patient-owned equipment or accessories, attachments, or options that modify base equipment, such as the addition of elevating leg rests to a manual wheelchair.

The Medicare definition of routinely purchased equipment under 42 CFR §414.220(a)(2) specifies that routinely purchased equipment means “equipment that was acquired by purchase on a national basis at least 75 percent of the time during the period July 1986 through June 1987. This definition was promulgated via an interim final rule (IFC) on December 7, 1992 (57 FR 57675), remaining consistent with Medicare program guidance in effect beginning in 1988 and discussed above, and finalized on July 10, 1995 (60 FR 35492). In the preamble of the 1992 IFC (57 FR 57679), we discussed how items were classified as routinely purchased DME based on data from July 1986 through June 1987, “in the absence of a statutory directive that defines the period for determining which items are routinely purchased.” CMS indicated that it “selected the period July 1, 1986 through June 30, 1987, because it is the same 12-month period required by section 1834(a)(2)(B)(i) of the Act for calculating the base fee schedule amount for routinely purchased equipment.” (57 FR 57679) This period was therefore established as the period from which data was used for identifying the items that had been acquired on a purchase basis 75 percent of the time or more under the Medicare rent/purchase program.

3. Payment for Inexpensive or Routinely Purchased Items and Capped Rental Items

Under §414.220(b), payment for inexpensive or routinely purchased DME is made on a purchase or rental basis, with total payments being limited to the purchase fee schedule amount
for the item. If an item is initially rented and then purchased, the allowed purchase charge is based on the lower of the actual charge or fee schedule amount for purchase of the item minus the cumulative allowed charge for previously paid rental claims. Under §414.229(f), payment for capped rental items is made on a monthly rental basis for up to 13 months of continuous use. The supplier must transfer title to the equipment to the beneficiary on the first day following the 13th month of continuous use.

B. Current Issues

Concerns have been raised about the application of the definition of and payment for routinely purchased DME, as it applies to expensive DME accessories. For example, recently one manufacturer of a new, expensive wheelchair accessory, included under a HCPCS code that would result in a corresponding Medicare fee schedule amount of approximately $3,000, if purchased, questioned why the HCPCS code describing their product was classified as capped rental DME. They pointed out that codes added to the HCPCS in recent years for other similar and more expensive wheelchair accessories costing $4,000 to $10,000 were classified as routinely purchased DME even though the items were not purchased under Medicare during the period specified in §414.220(b). As a result, we began a review of expensive items that have been classified as routinely purchased equipment since 1989, that is, new codes added to the HCPCS after 1989 for items costing more than $150, to address this apparent inconsistency.

As a result of this review, we found some codes that are not classified consistent with the regulatory definition of routinely purchased equipment at section §414.220(a)(2). We found that HCPCS codes added after 1989 for expensive, durable accessories used with base equipment, such as wheelchairs, have been classified as routinely purchased equipment. While section 1834(a)(2)(A)(iii) of the Act and 42 CFR §414.220(a)(3) of the regulations allow payment for
the purchase of accessories used in conjunction with nebulizers, aspirators, continuous positive airway pressure devices (CPAP), other items covered under the DME benefit, including DME other than nebulizers, aspirators, CPAP devices, respiratory assist devices and accessories used in conjunction with those items, are paid for in accordance with the rules at section 1834(a) of the Act and are classified under sections 1834(a)(3) thru (7) of the Act as inexpensive and other routinely purchased DME, items requiring frequent and substantial servicing, certain customized items, oxygen and oxygen equipment, other covered items other than DME, or other covered items of DME.

Additionally, we found that in some cases, expensive items of DME were classified as routinely purchased based on information suggesting that payers other than Medicare were routinely making payment for the items on a purchase basis. We believe that classifying an item as routinely purchased equipment based on data and information from other payers for the purposes of implementing §414.220(b) is inappropriate because other payers do not operate under the same payment rules as Medicare. Other payers may decide to purchase expensive items for reasons other than achieving a more economical alternative to rental, the basis Medicare contractors used in deciding whether to purchase items during July 1986 through June 1987. In other cases, expensive items of DME were classified as routinely purchased equipment based on requests from manufacturers of equipment primarily used by Medicaid beneficiaries. We do not believe we should classify an item as routinely purchased equipment for the purposes of implementing §414.220(b) of the Medicare regulations based on how this might affect other payers such as Medicaid state agencies because such classifications are not consistent with the regulations. After reviewing this issue, we do not think the regulation supports the classification of expensive DME as routinely purchased equipment based on whether other payers routinely
pay for the item on a purchase basis or how manufacturers would prefer that other payers pay for
the item. The classification of HCPCS codes for expensive equipment added after 1989 as
routinely purchased equipment based on this kind of information does not comply with the
Medicare definition of routinely purchased equipment and defeats a fundamental purpose of the
capped rental payment methodology to avoid paying the full purchase price of costly equipment
when used only a short time.

DME and accessories used in conjunction with DME are paid for under the DME benefit
and in accordance with the rules at section 1834(a) of the Act. In the proposed rule (78 FR
40874), we proposed to clarify the existing definition of routinely purchased equipment at
§414.220(a)(2) and provide notice that certain HCPCS codes for DME and DME accessories
added to the HCPCS after 1989 that are currently classified as routinely purchased equipment
would be reclassified as capped rental items (see Table 11 below). Under our proposal, this
would apply to all expensive items for which Medicare claims data from July 1986 through June
1987 does not exist or does not indicate that the item was acquired by purchase on a national
basis at least 75 percent of the time. In the case of expensive accessories that are furnished for
use with complex rehabilitative power wheelchairs, we proposed that the purchase option for
complex rehabilitative power wheelchairs at section 1834(a)(7)(A)(iii) of the Act would also
apply to these accessories. For any wheelchair accessory classified as a capped rental item and
furnished for use with a complex rehabilitative power wheelchair (that is, furnished to be used as
part of the complex rehabilitative power wheelchair), the supplier must give the beneficiary the
option of purchasing these accessories at the time they are furnished. These items would be
considered as part of the complex rehabilitative power wheelchair and associated purchase
option set forth at §414.229(a)(5).
We also solicited comments on the effective date(s) for reclassifying items previously classified as routinely purchased equipment to the capped rental payment class in order to be in compliance with current regulations. (78 FR 40874) Given that some items (HCPCS codes) may be included in the Round 2 and/or Round 1 Recompete phases of the competitive bidding program (CBP), we indicated we do not believe we could change the classification for items furnished under these programs until the contracts awarded based on these competitions expire on July 1, 2016, and January 1, 2017, respectively, regardless of whether the item is provided in an area subject to competitive bidding or not. We proposed that the reclassification of items previously classified as routinely purchased equipment to the capped rental payment class be effective January 1, 2014, for all items that are not included in either a Round 2 or Round 1 Recompete CBP established in accordance with §414.400. For any item currently under a Round 2 CBP, instead of a January 1, 2014, effective date we proposed July 1, 2016, for these reclassifications, which would apply to all items furnished in all areas of the country, with the exception of items furnished in a Round 1 Recompete CBP. For items furnished in a Round 1 Recompete CBP, we proposed an effective date of January 1, 2017, which would only apply to items furnished in the nine Round 1 Recompete areas. Therefore, we proposed to generally base the effective dates on when the CBPs end. To summarize, the proposed effective dates for the reclassifications of these items from the routinely purchased DME class to the capped rental DME class would be:

- January 1, 2014, for items furnished in all areas of the country if the item is not included in Round 2 or Round 1 Recompete CBP;

- July 1, 2016, for items furnished in all areas of the country if the item is included in a Round 2 CBP and not a Round 1 Recompete CBP and for items included in a Round 1
Recompete CBP but furnished in an area other than one of the 9 Round 1 Recompete areas; and

- January 1, 2017, for items included in a Round 1 Recompete CBP and furnished in one of the nine Round 1 Recompete areas.

We noted that this implementation strategy would allow the item to be moved to the payment class for capped rental items at the same time in all areas of the country without disrupting CBPs currently underway. For Round 1 Recompete items furnished in nine areas of the country for the six-month period from July 1, 2016, thru December 31, 2016, Medicare payment would be on a capped rental basis in all parts of the country other than these nine areas.

Alternatively, we noted the effective date for the reclassifications could be January 1, 2014, for all items paid under the fee schedule (78 FR 40875). In other words, the reclassification would not affect payments for items furnished under the Round 2 or Round 1 Recompete CBPs in the respective competitive bidding areas (CBAs) until the contract entered into under these programs expire on July 1, 2016, and January 1, 2017, respectively. However, such an alternative would result in an extensive two and a half year period from January 2014 through June 2016, where Medicare payment would be on a capped rental basis for the items in half of the country (non-CBAs) and on a purchase basis in the other half of the country (109 Round 2 and/or Round 1 Recompete CBAs). We believed that this bifurcation in payment classifications would create confusion and would be difficult to implement, but we solicited comments on this alternative implementation strategy.

For this final rule, we have identified 78 HCPCS codes that will require reclassification from the inexpensive or routinely purchased DME payment class to the capped rental DME payment class (78 FR 40875 through 40876). The codes are shown in Table 11 below. As
shown in Table 11, Column A of the table shows the type of DME, Columns B and C indicate the HCPCS level II codes and the short descriptor. The long descriptor for each code is available at http://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS.html.

As shown in Column A, the majority of codes relate to manual wheelchairs and wheelchair accessories. In the case of accessories used with complex rehabilitative power wheelchairs, the purchase option for complex rehabilitative power wheelchairs applies to these accessories because they are part of the complex rehabilitative power wheelchair.

### Table 11 Routinely Purchased Items Reclassified to Capped Rental

<table>
<thead>
<tr>
<th>Group Category</th>
<th>HCPCS</th>
<th>Descriptor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Automatic External Defibrillator</td>
<td>K0607</td>
<td>Repl battery for AED</td>
</tr>
<tr>
<td>Canes/Crutches</td>
<td>E0117</td>
<td>Underarm spring assist crutch</td>
</tr>
<tr>
<td>Glucose Monitor</td>
<td>E0620</td>
<td>Capillary blood skin piercing device laser</td>
</tr>
<tr>
<td>High Frequency Chest Wall Oscillation Device (HFCWO)</td>
<td>A7025</td>
<td>Replace chest compress vest</td>
</tr>
<tr>
<td>Hospital Beds/Accessories</td>
<td>E0300</td>
<td>Enclosed ped crib hosp grade</td>
</tr>
<tr>
<td>Misc. DMEPOS</td>
<td>A4639</td>
<td>Infrared ht sys replacement pad</td>
</tr>
<tr>
<td></td>
<td>E0762</td>
<td>Trans elec jt stim dev sys</td>
</tr>
<tr>
<td></td>
<td>E1700</td>
<td>Jaw motion rehab system</td>
</tr>
<tr>
<td>Nebulizers &amp; Related Drugs</td>
<td>K0730</td>
<td>Ctrl dose inh drug deliv system</td>
</tr>
<tr>
<td>**r</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other Neuromuscular Stimulators</td>
<td>E0740</td>
<td>Incontinence treatment system</td>
</tr>
<tr>
<td></td>
<td>E0764</td>
<td>Functional neuromuscular stimulation</td>
</tr>
<tr>
<td>Pneumatic Compression Device</td>
<td>E0656</td>
<td>Segmental pneumatic trunk</td>
</tr>
<tr>
<td></td>
<td>E0657</td>
<td>Segmental pneumatic chest</td>
</tr>
<tr>
<td>Power Operated Vehicles (POV)</td>
<td>E0984</td>
<td>Add pwr tiller</td>
</tr>
<tr>
<td>***</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Speech Generating Devices</td>
<td>E2500</td>
<td>SGD digitized pre-rec &lt;=8min</td>
</tr>
<tr>
<td></td>
<td>E2502</td>
<td>SGD prerec msg &gt;8min &lt;=20min</td>
</tr>
<tr>
<td></td>
<td>E2504</td>
<td>SGD prerrec msg&gt;20min &lt;=40min</td>
</tr>
<tr>
<td></td>
<td>E2506</td>
<td>SGD prerrec msg &gt; 40 min</td>
</tr>
<tr>
<td></td>
<td>E2508</td>
<td>SGD spelling phys contact</td>
</tr>
<tr>
<td></td>
<td>E2510</td>
<td>SGD w multi methods messg/access</td>
</tr>
<tr>
<td>Support Surfaces</td>
<td>E0197</td>
<td>* Air pressure pad for mattress</td>
</tr>
<tr>
<td></td>
<td>E0198</td>
<td>Water pressure pad for mattress</td>
</tr>
<tr>
<td>Traction Equipment</td>
<td>E0849</td>
<td>Cervical pneum traction equip</td>
</tr>
<tr>
<td></td>
<td>E0855</td>
<td>Cervical traction equipment</td>
</tr>
<tr>
<td></td>
<td>E0856</td>
<td>Cervical collar w air bladder</td>
</tr>
<tr>
<td>Walkers</td>
<td>E0140</td>
<td>* Walker w trunk support</td>
</tr>
<tr>
<td></td>
<td>E0144</td>
<td>Enclosed walker w rear seat</td>
</tr>
<tr>
<td>Group Category</td>
<td>HCPCS</td>
<td>Descriptor</td>
</tr>
<tr>
<td>----------------------------</td>
<td>---------</td>
<td>-----------------------------------</td>
</tr>
<tr>
<td>E0149 *</td>
<td>Heavy duty wheeled walker</td>
<td></td>
</tr>
<tr>
<td>E1161</td>
<td>Manual adult wc w tiltin spac</td>
<td></td>
</tr>
<tr>
<td>E1232</td>
<td>Folding ped wc tilt-in-space</td>
<td></td>
</tr>
<tr>
<td>E1233</td>
<td>Rig ped wc tiltin spac w/o seat</td>
<td></td>
</tr>
<tr>
<td>E1234</td>
<td>Fld ped wc tiltin spac w/o seat</td>
<td></td>
</tr>
<tr>
<td>E1235</td>
<td>Rigid ped wc adjustable</td>
<td></td>
</tr>
<tr>
<td>E1236</td>
<td>Folding ped wc adjustable</td>
<td></td>
</tr>
<tr>
<td>E1237</td>
<td>Rgd ped wc adjstabl w/o seat</td>
<td></td>
</tr>
<tr>
<td>E1238</td>
<td>Fld ped wc adjstabl w/o seat</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Wheelchairs Options/Accessories</th>
<th>HCPCS</th>
<th>Descriptor</th>
</tr>
</thead>
<tbody>
<tr>
<td>E0985 *</td>
<td>W/c seat lift mechanism</td>
<td></td>
</tr>
<tr>
<td>E0986</td>
<td>Man w/c push-rim pow assist</td>
<td></td>
</tr>
<tr>
<td>E1002 ^</td>
<td>Pwr seat tilt</td>
<td></td>
</tr>
<tr>
<td>E1003 ^</td>
<td>Pwr seat recline</td>
<td></td>
</tr>
<tr>
<td>E1004 ^</td>
<td>Pwr seat recline mech</td>
<td></td>
</tr>
<tr>
<td>E1005 ^</td>
<td>Pwr seat recline pwr</td>
<td></td>
</tr>
<tr>
<td>E1006 ^</td>
<td>Pwr seat combo w/o shear</td>
<td></td>
</tr>
<tr>
<td>E1007 ^</td>
<td>Pwr seat combo w/shear</td>
<td></td>
</tr>
<tr>
<td>E1008 ^</td>
<td>Pwr seat combo pwr shear</td>
<td></td>
</tr>
<tr>
<td>E1010 ^</td>
<td>Add pwr leg elevation</td>
<td></td>
</tr>
<tr>
<td>E1014</td>
<td>Reclining back add ped w/c</td>
<td></td>
</tr>
<tr>
<td>E1020 *</td>
<td>Residual limb support system</td>
<td></td>
</tr>
<tr>
<td>E1028 *</td>
<td>W/c manual swingaway</td>
<td></td>
</tr>
<tr>
<td>E1029</td>
<td>W/c vent tray fixed</td>
<td></td>
</tr>
<tr>
<td>E1030 ^</td>
<td>W/c vent tray gimbaled</td>
<td></td>
</tr>
<tr>
<td>E2227</td>
<td>Gear reduction drive wheel</td>
<td></td>
</tr>
<tr>
<td>E2228 *</td>
<td>Mwc acc, wheelchair brake</td>
<td></td>
</tr>
<tr>
<td>E2310 ^</td>
<td>Electro connect btw control</td>
<td></td>
</tr>
<tr>
<td>E2311 ^</td>
<td>Electro connect btw 2 sys</td>
<td></td>
</tr>
<tr>
<td>E2312 ^</td>
<td>Mini-prop remote joystick</td>
<td></td>
</tr>
<tr>
<td>E2313 ^</td>
<td>PWC harness, expand control</td>
<td></td>
</tr>
<tr>
<td>E2321 ^</td>
<td>Hand interface joystick</td>
<td></td>
</tr>
<tr>
<td>E2322 ^</td>
<td>Mult mech switches</td>
<td></td>
</tr>
<tr>
<td>E2325 ^</td>
<td>Sip and puff interface</td>
<td></td>
</tr>
<tr>
<td>E2326 ^</td>
<td>Breath tube kit</td>
<td></td>
</tr>
<tr>
<td>E2327 ^</td>
<td>Head control interface mech</td>
<td></td>
</tr>
<tr>
<td>E2328 ^</td>
<td>Head/extremity control interface</td>
<td></td>
</tr>
<tr>
<td>E2329 ^</td>
<td>Head control interface nonproportional</td>
<td></td>
</tr>
<tr>
<td>E2330 ^</td>
<td>Head control proximity switch</td>
<td></td>
</tr>
<tr>
<td>E2351 ^</td>
<td>Electronic SGD interface</td>
<td></td>
</tr>
<tr>
<td>E2368 *</td>
<td>Pwr drivewheel motor replace</td>
<td></td>
</tr>
<tr>
<td>E2369 *</td>
<td>Pwr drivewheel gear box replace</td>
<td></td>
</tr>
<tr>
<td>E2370 *</td>
<td>Pwr wc dr wh motor/gear comb</td>
<td></td>
</tr>
<tr>
<td>E2373 ^</td>
<td>Hand/chin ctrl spec joystick</td>
<td></td>
</tr>
<tr>
<td>E2374 ^</td>
<td>Hand/chin ctrl std joystick</td>
<td></td>
</tr>
<tr>
<td>E2375 *</td>
<td>Non-expandable controller</td>
<td></td>
</tr>
<tr>
<td>E2376 ^</td>
<td>Expandable controller, replace</td>
<td></td>
</tr>
<tr>
<td>E2377 ^</td>
<td>Expandable controller, initial</td>
<td></td>
</tr>
<tr>
<td>E2378</td>
<td>Pw actuator replacement</td>
<td></td>
</tr>
<tr>
<td>K0015 *</td>
<td>Detach non-adjus hght armrst</td>
<td></td>
</tr>
<tr>
<td>K0070 *</td>
<td>Rear whl complete pneum tire</td>
<td></td>
</tr>
</tbody>
</table>

| Wheelchairs Seating           | E0955 *                         | Cushioned headrest                  |
In summary, we provided notice that certain HCPCS codes we proposed would be reclassified as capped rental items. We invited comments on this section.

C. Responses to Comments on the Clarification of the Definition of Routinely Purchased Durable Medical Equipment (DME)

We received approximately 172 comments regarding the clarification of the definition of Routinely Purchased DME. CMS received comments from DME suppliers, manufacturers, professional, state and national trade associations, physicians, physical therapists (PTs), speech pathologists, occupational therapists (OTs), beneficiaries and their caregivers, the Veterans Administration (VA), and a state government representative. The comments and our responses are summarized below.

Comment: Several commenters noted the clarification of the definition of routinely purchased durable medical equipment relies on 1986/87 as the base year and instead suggested using 2010/11 as a base year for determining new items classified under routinely purchased category.

Response: We do not agree with this comment. In this final rule, we are not revising the definition given our longstanding interpretation regarding section 1834(a)(2) of the Act. Although there have been numerous amendments to section 1834(a) over the years to address payment of certain DME, there have been no amendments to revise the definition of routinely purchased DME. Payment on a capped rental basis avoids lump sum purchases of expensive equipment that is only needed on a short term basis and is more economical than purchase. If the equipment is needed on a long term basis, beneficiaries will take over ownership following 13
months of continuous use. In addition, we did not propose to revise the base period in the
definition for routinely purchased DME at 42 CFR §414.220(a)(2). We are therefore not
adopting this suggestion to revise the base period for the definition of routinely purchased DME
equipment under 42 CFR §414.220(a)(2).

Comment: Many commenters contended that reclassifying certain codes from the
routinely purchased DME category to capped rental DME would result in additional
administrative burden for suppliers. Commenters reacted unfavorably to repeated billings for
monthly rental claims for as long as the item is medically necessary up until title transfers at the
end of the 13th month rental period.

Response: While we understand certain billing procedures for capped rental items differ
from and may be more administratively burdensome than billing procedures for routinely
purchased items, this does not negate the fact that items must be classified in accordance with the
rules of the statute and regulations.

Comment: One commenter requested a delay in the implementation of the
reclassification of the list of codes in our table from routinely purchased DME to capped rental
DME. The commenter stated that more time is needed to educate practitioners and patients
along with receipt of adequate program guidance. Another comment from a manufacturer
requested a substantial delay in implementation of the capped rental system for Speech
Generating Devices (SGDs).

Response: Items that are not in compliance with the existing definition of routinely
purchased DME will be classified as capped rental items and paid for in accordance with the
rules set forth in 42 CFR 414.229 for items not currently included in a CBP that are furnished on
or after April 1, 2014. The dates for re-classification of items affected by this rule that are
currently included in a CBP will be discussed later in the preamble. We do not agree with the comment that a substantial delay in implementation of the reclassification of SGDs is necessary. Suppliers and practitioners will have more than three months to become familiar with payment rules and billing procedures related to capped rental items and to prepare for this change in classification. In addition, this change in classification only affects payments for these items on or after April 1, 2014. We recognize that consumers, occupational and physical therapists and disability advocacy groups have expressed concerns with these changes to acquisition policy for some durable medical equipment which persons with disabilities rely upon, including specialized wheelchairs and speech generating devices. Although we do not anticipate disruptions resulting from the transition from purchase to a capped rental, we understand the important role that this technology plays in maximizing the independence of persons with disabilities and their ability to direct their own care. Accordingly, CMS is committed to carefully monitoring beneficiary access using real-time claims data to ensure that there isn’t an adverse impact.

**Comment**: Several commenters noted some of the codes proposed for reclassification include the term “replacement only”, such as code E2376 Expandable controller, replacement and K0607 Automatic external defibrillator part; thus, the codes are most likely submitted for payment for beneficiary owned DME instead of DME owned by the supplier during a 13-month capped rental period. Commenters felt it was unrealistic to expect a supplier to rent these items and disable the patient owned equipment should the beneficiary become ineligible for Medicare payment. Another commenter mentioned that some of the transitioning codes are not covered or have lower utilization under Medicare.

**Response**: We do not agree with these comments. The statute does not differentiate between items paid for under the DME benefit that are base equipment versus items paid for
under the DME benefit that are replacement parts for base equipment. With the exception of drugs, which are paid in accordance with a separate payment methodology, all items covered under the DME benefit category are subject to the payment rules mandated by section 1834(a) of the Act. An item is not classified based on utilization, and, under our regulation at 42 CFR 414.229(f), if the beneficiary needs the item for 13 continuous months, title to the item is transferred to the beneficiary after 13 months. Lastly, our review of the codes for reclassification from routinely purchased DME to capped rental indicates coverage under Medicare although the extent of coverage differs by item.

Comment: One commenter noted several of the listed codes have limited coverage under Medicare and so continuing to pay on a lump sum purchase basis for these items will have a minimal impact on Medicare expenditures.

Response: The statute does not provide direction or discretion to classify items under section 1834(a)(2) thru (7) of the Act based on magnitude of expenditures.

Comment: Numerous commenters opposed reclassifying the HCPCS codes for pediatric manual wheelchairs (codes E1232 – E1238) and manual tilt in space wheelchairs (code E1161) from the payment class for inexpensive or routinely purchased items to the payment class for capped rental items. Some commenters stated many adult tilt in space wheelchair users require customization of equipment and require adjustment to reflect their unique postural and mobility needs. The commenters stated a concern that payment on a rental basis for these items will increase the risk for orthopedic deformities due to improper support, increase the risk of pressure sores from poorly managed skin integrity, and will contribute to overall costs of medical care. Many commenters stated these items are used for chronic conditions or permanent disabilities, such as quadriplegia, paraplegia, multiple sclerosis, head and spinal injuries, requiring
wheelchairs and wheelchair accessories that are constructed of components that are not mass produced which reduces the profit margin compared to the furnishing of power mobility and acute adult manual wheelchairs.

**Response:** Claims for “youth” or “pediatric” wheelchairs were submitted using HCPCS code E1091 (Youth Wheelchair, Any Type) from July 1986 through June 1987, and this equipment was paid on a purchase basis 25 percent of the time during this time. This is well below the 75 percent threshold established in the statute; and therefore, classification of pediatric or youth wheelchairs (HCPCS codes E1232 – E1238) as capped rental items is required by the regulations. The data from July 1986 through June 1987 also indicates that only 30 percent of all manual wheelchairs were purchased for Medicare beneficiaries during this time. As Medicare claims data from July 1986 through June 1987 does not exist for adult tilt in space wheelchairs (HCPCS code E1161), the data required by the regulation to classify these items as routinely purchased equipment does not exist and these items will therefore be classified as capped rental items in accordance with this rule. We agree that some items may have a higher cost because they are not mass produced; however, such costs are accounted for in the fee schedule amounts that have been set based on supplier charges or price lists. We note that the fee schedule amounts for the pediatric and adult tilt in space manual wheelchairs are more than double, and in some cases triple, the fee schedule amounts established for other manual wheelchairs. We recognize that commenters have expressed concerns with these changes to payment policy for some durable medical equipment which persons with disabilities rely upon, including specialized wheelchairs. Although we do not anticipate disruptions resulting from the transition from purchase to a capped rental, we understand the important role that this equipment plays in maximizing the independence of persons with disabilities and their ability to direct their own
care. Accordingly, CMS is committed to carefully monitoring beneficiary access using real-time claims data to ensure that there isn’t an adverse impact.

Comment: One commenter raised concern that suppliers spend multiple hours on supplies, labor and parts to customize a wheelchair; therefore, if patients become temporarily institutionalized, regress and need new customized parts, or pass away so that the wheelchair is returned to the supplier, the supplier would have a need to readjust and customize the chair to fit the needs of the next patient.

Response: This rule has no impact on items that meet the definition of customized items at 42 CFR 414.224. For items that are affected by this rule, we agree that some items may have a higher cost because they are not mass produced; however, such costs are accounted for in the fee schedule amounts that have been set based on supplier charges or price lists. We appreciate hearing about the concerns with these changes to payment policy for some durable medical equipment which persons with disabilities rely upon, including specialized wheelchairs. Although we do not anticipate disruptions resulting from the transition from purchase to a capped rental, we understand the important role that this technology plays in maximizing the independence of persons with disabilities and their ability to direct their own care. Accordingly, CMS is committed to carefully monitoring beneficiary access using real-time claims data to ensure that there isn’t an adverse impact.

Comment: There were concerns raised by many commenters regarding reclassification of wheelchair options and accessories added to individually configure wheelchairs to meet long-term mobility needs.

Response: In this final rule, an exception is established so that wheelchair options and accessories furnished for use with purchased complex rehabilitative power wheelchairs can be
paid under a routinely purchased basis consistent with 42 CFR 414.229(a)(5). Other expensive wheelchair options and accessories that are paid separate from the rental payments for the wheelchair base and were not routinely purchased from July 1986 through June 1987 fall under the payment category for capped rental items. Payment will therefore be made on a capped rental basis for the options and accessories furnished for use with the rented wheelchair base. As a result, when payment for less than 13 months of continuous use is made for the wheelchair and associated options and accessories, the supplier can furnish the equipment to other patients and receive additional payment for the equipment. If payment is made for 13 months of continuous use of the wheelchair, then title to the wheelchair and all options and accessories will transfer to the beneficiary.

**Comment:** One commenter recommended CMS should establish that all manual wheelchairs should remain in the routinely purchased category and that options and accessories provided with/for a “routinely purchased” wheelchair base should be considered “routinely purchased” as well.

**Response:** With the exception of ultralightweight manual wheelchairs, manual wheelchairs were not routinely purchased under the Medicare program from July 1986 through June 1987. The data from July 1986 through June 1987 indicates that only 30 percent of manual wheelchairs and 55 percent of power wheelchairs were purchased for Medicare beneficiaries during this time. These percentages are well below the 75 percent threshold established in the statute. As discussed above, an exception is established so that wheelchair options and accessories furnished for use with purchased complex rehabilitative power wheelchairs can be paid under a routinely purchased basis consistent with 42 CFR 414.229(a)(5). Wheelchair options and accessories falling under the payment category for capped rental items will be paid
for on a rental basis when they are furnished with other wheelchair bases, with title to the equipment transferring to the beneficiary after 13 months of continuous use.

Comment: Many commenters complained that a capped rental payment method will result in a significant financial burden for suppliers who may face challenges securing capital/lines of credit in the current economic environment.

Response: We do not agree with this comment. The capped rental payment method allows suppliers to reclaim capital equipment that is not needed for 13 months of continuous use. While Medicare payments may total 105 percent of the historic purchase price over 13 months of continuous use by a single beneficiary, the item could be rented for significantly more than 13 monthly payments and significantly more than 105 percent of the historic purchase price if it is used by multiple beneficiaries who do not need the item for the full 13 months.

Comment: Commenters stated that the proposed change in payment rules will be adopted by payers other than Medicare and therefore should not be adopted.

Response: Speculation about how other payers will pay for items that are also paid for by Medicare is beyond the scope of this rule and we have not taken such things into consideration when finalizing our policies. We must comply with the requirements of section 1834(a)(2) through (7) of the Act regarding how we classify and pay for DME items.

Comment: Various commenters argued that since the ultralightweight wheelchair (HCPCS code K0005) is classified as routinely purchased equipment, other complex rehabilitative manual wheelchairs (HCPCS codes E1161 and E1232 through E1238) should similarly be classified as routinely purchased equipment.

Response: The ultralightweight wheelchair was classified as routinely purchased equipment based on the regulatory standard (that is, it was acquired for purchase on a national
basis at least 75 percent of the time from July 1986 through June 1987). Other manual wheelchairs have not been routinely purchased under the Medicare program. Claims for “youth” or “pediatric” wheelchairs were submitted using HCPCS code E1091 (Youth Wheelchair, Any Type) from July 1986 through June 1987, and this equipment was paid on a purchase basis 25 percent of the time during this time. This is well below the 75 percent threshold established in the statute; and therefore, classification of pediatric or youth wheelchairs (HCPCS codes E1232 – E1238) as capped rental items is required by the regulations. The data from July 1986 through June 1987 also indicates that only 30 percent of all manual wheelchairs were purchased for Medicare beneficiaries during this time. As Medicare claims data from July 1986 through June 1987 does not exist for adult tilt in space wheelchairs (HCPCS code E1161), these items will be classified as capped rental items in accordance with this rule, and this is consistent with the classification of youth or pediatric wheelchairs and for manual wheelchairs in general based on Medicare claims data from July 1986 through June 1987.

**Comment:** One commenter concurred with our proposal by indicating it is a waste for patients at end stage of life to purchase complex wheelchairs which they then would not use for more than 1-2 years, due to various life ending diseases or due to regression in function, or at an older terminal age. The commenter noted it is advisable to have a system of rental and return, so that the same equipment can be modified, then rented to someone else. This will greatly reduce waste in this area of assistive technology/wheelchair supply and demand.

**Response:** We appreciate this comment.

**Comment:** Several commenters supported our proposal permitting a supplier to give the beneficiary the option of purchasing a wheelchair accessory classified as a capped rental item and furnished for use with a complex rehabilitative power wheelchair (that is, furnished to be
used as part of the complex rehabilitative power wheelchair) at the time the accessory is furnished. These wheelchair accessory items would be considered as part of the complex rehabilitative power wheelchair and associated purchase option set forth at §414.229(a)(5).

Response: We appreciate this comment.

Comment: Several commenters urged CMS to extend our proposal to permit a supplier to give the beneficiary the option of purchasing a wheelchair accessory classified as a capped rental item and furnished for use with a complex rehabilitative power wheelchair (that is, furnished to be used as part of the complex rehabilitative power wheelchair) to accessories furnished for use with standard power wheelchairs.

Response: We disagree with this comment. The statute does not provide a purchase option for standard power wheelchairs. Section 1834(a)(7)(A)(iii) provides the purchase agreement option only for complex, rehabilitative, power-driven wheelchairs.

Comment: Some commenters were concerned that Part B coverage and payment for rented DME is no longer allowed when a beneficiary enters a hospital, so the beneficiary will be billed for equipment during the time the beneficiary is in the hospital because the provider would not be able to remove a tilt mechanism from their wheelchair without rendering their chair non-functional.

Response: The Part B benefit for DME and the payment rules at section 1834(a) of the Act do not extend to DME items furnished for use in hospitals. Classification of items under the payment classes established in sections 1834(a)(2) through (7) is not affected by whether or not the item will later be available for use in a hospital. Medicare benefit payments for items used in hospitals may be available under other parts of the program other than the Part B benefit for DME. In addition, suppliers are responsible for submitting claims for payment under the
Medicare Part B DMEPOS fee schedule in compliance with our regulations and program instructions, such as those in the Medicare Claims Processing Manual (Pub 100.04), chapter 20, section 30.5.4 which address such temporary interruptions

**Comment:** Several commenters argued that the estimated program savings are not accurate primarily because the 8 month average use assumed for the items moved from routinely purchased to capped rental is in error because the 8 month average use was established for existing capped rental items, not routinely purchased.

**Response:** We believe that Medicare data on the average number of monthly rental claims paid for items currently classified as capped rental items is a reasonable proxy for the average number of monthly rental claims that will be paid for items reclassified as a result of this rule and provides an accurate estimate of the impact of this rulemaking on Medicare part B expenditures for DME. Most of the items being reclassified are either wheelchairs or wheelchair accessories. In reviewing the data used to determine that an average of 8 monthly rental payments are made for items currently classified as capped rental items, the average number of paid monthly rental claims per beneficiary drops to 7 when only wheelchairs and wheelchair accessories currently classified as capped rental item are considered. Our goal is to create a reasonable model by which to estimate the fiscal impact of the policy. The method used to calculate the savings is as follows:

- Sum the 2011 allowed charges for the HCPCS that are affected
- Increase the allowed charges by Medicare Advantage add-on
- Apply the annual increases for fee-for-service Medicare Part B population and for fee update to the total expenditures through the year 2023
• Based on claims data, the average duration of use of capped rental equipment is approximately 8 months, which is 2/3 of purchase price.

• So it is assumed that moving an item from routinely purchased to capped rental will on average save 33 percent of the purchased price, which is the factor applied to allowed charges to generate the savings indicated in the proposed rule.

Comment: Several commenters argued that the estimated savings in the rule does not consider the cost of possible increased institutional care.

Response: We do not believe the policy described in this final rule would increase the use of institutional care. We are not reducing the number of items that would be covered or reducing payment for certain DME items such that more institutional care may be needed.

Comment: Some commenters recommended classifying equipment as routinely purchased equipment if any of the following conditions are met: 1) the item is routinely needed for a period exceeding 13 months; 2) the item is intended for use by people with permanent disabilities; 3) the item is designed, manufactured, or assembled for a single individual (not intended to be used by multiple individuals); 4) the item was previously classified as routinely purchased equipment; and 5) other payers routinely pay for the item on a purchase basis.

Response: We disagree with this suggestion. We have interpreted the statutory definition of routinely purchased equipment, as set forth in the regulations, as “equipment that was acquired by purchase on a national basis at least 75 percent of the time during the period July 1986 through June 1987.” The statute does not contemplate use of additional factors in making determinations regarding whether equipment is routinely purchased, such as the ones raised by the commenters. Also, we see no reason to revise the longstanding definition of routinely purchased equipment, but we may reconsider the issue in the future if necessary.
Comment: One commenter noted the United States Supreme Court held in Olmstead v. L.C. (527 US 581 (1991)) that unjustified segregation of persons with disabilities constitutes discrimination in violation of title II of the Americans with Disabilities Act. As noted by the commenter, the Court held that public entities must provide community-based services to persons with disabilities to support them to live independently in the community. The commenter asserts a change in the terms of usage of assistive devices jeopardizes the spirit of the decision made in the Olmstead case. A person can be in a position of not having these devices at time of need.

Response: We do not concur that changing the payment classification of certain codes from routinely purchased DME to capped rental DME jeopardizes the spirit of the decision made in the Olmstead case. Our proposal is not designed to undermine payment of the items; rather it is clarifying the definition of routinely purchased equipment set forth at section §414.220(a)(2) and reclassifying some codes that are not presently classified consistent with the regulatory definition. In addition, the proposal is not designed to have any impact on coverage of items and services under the Medicare Part B benefit for DME. Such items and services would continue to be available consistent with the statute and regulations. This rule is designed to clarify the payment provisions applicable to accessories used in conjunction with items paid for under section 1834(a) of the Act.

Comment: Some commenters stated that speech generating devices (SGDs) (HCPCS codes E2500 – E2510) should not be covered as DME but instead as prosthetic devices.

Response: These comments are outside the scope of the proposed rule, and therefore are not addressed in this final rule. The process for reviewing coverage/benefit category for an item
is not addressed in this rule. Information on the process can be found at the website 

Comment: Several commenters stated that certain patients may benefit from renting 
SGDs. One commenter wrote once an individual has the initial assessment, there is often a trial 
period with one or more devices. The average time for trials is 90 days. One commenter stated a 
rental may be appropriate for short-term use such as a temporary loss of natural speech due to a 
surgical procedure or when waiting to purchase one. Another commenter indicated patients may 
benefit from renting a device for up to 1 year. Furthermore, one commenter supported 
implementation of a rental payment basis for certain DME to prevent abuse of the purchase basis 
system and to help keep co-insurance costs lower when extended over the number of rental 
months.

Response: We thank the commenters for their helpful comments and agree about the 
potential benefits of our capped rental policy. We are aware that some manufacturers make their 
SGC products available on a rental basis so that patients can try out the products to figure out 
which one best meets their needs. Under the capped rental payment system, the patient will have 
the ability to obtain a new physician order and change equipment during the rental period to 
equipment that better meets their medical needs while Medicare rental payments continue up to 
the point where title to the equipment transfers to the beneficiary after 13 months of continuous 
use..

Comment: Numerous commenters opposed reclassification of SGDs, indicating that 
these devices are individually programmed based on each patient's need and access method (that 
is, eye-gaze, touch screen, switch) and language skills. The commenters stated that these devices 
are not similar to wheelchairs which are primarily generic in their design and can be used by a
wide variety of individuals without significant modifications. Also, the commenters reviewed that patients’ caregivers may be accustomed to specific devices used by their patients. One commenter suggested that a SGD is more appropriately analyzed as a complex rehabilitation tool, and as part of that analysis, the importance of integration and customization with the other rehab tools and medical needs of the patient must be considered. Other commenters reiterated that SGDs assist with communication that is essential for an individual's independence and functional living. Another commenter described an analysis of the diagnoses of the patients using SGDs, which shows that an estimate of eight months for a rental is unrealistic given that many SGD patients have a long term need for the device.

Response: We recognize that patients may use long term DME such as SGDs because of chronic conditions or permanent disabilities; however, we believe assigning the appropriate payment category in accordance with the statute and regulations ensures appropriate payment, supplier responsibilities, and beneficiary safeguards. Our final policy is not designed to interfere with patient care or a practitioner’s efforts to program SGDs.

Comment: Many commenters claimed that reclassifying SGDs from routinely purchased DME to capped rental DME would cause suppliers to limit the amount of time and attention given to furnishing quality SGDs. Several commenters are concerned suppliers will require patients to switch devices and the devices would be taken away from patients who need them when the patient has reached maximum rental fees. Another commenter raised concerns that suppliers will not furnish SGDs that adequately serves patients who move from one location to another.

Response: The HCPCS codes for SGDs and other DME describe different categories of items. The supplier must furnish the item ordered by the physician to meet the patient’s medical
needs as required by 42 CFR 424.57(c)(4). Suppliers that are found not in compliance with the DMEPOS supplier standards are not allowed to possess a supplier number and receive Medicare payment for DME in accordance with section 1834(j) of the Act. These standards and requirements are not affected by the methodology used to pay for the item. In addition, regulations at 42 CFR 414.229(g) require that suppliers furnishing capped rental items continue to furnish the item for the full 13-month capped rental period with very limited exceptions and are prohibited from switching the patient’s equipment unless the physician orders different equipment, the beneficiary chooses to obtain a newer technology item or an upgraded item, or the equipment is replaced because of loss, theft, or irreparable damage or wear. If the device is used for 13 continuous months, then the supplier is required to transfer title to the equipment to the beneficiary. Regarding patients who relocate near the end of the capped rental period and need to find a new supplier, CMS has been able to work with suppliers of capped rental items in the past to ensure beneficiary access in these situations.

Comment: Numerous comments were concerned that a rental payment method would impact access to SGDs in certain settings such as a hospital or nursing facility. As a result, commenters were concerned because the patient should not need to worry that the device will be taken away when circumstances require the patient to communicate to practitioners in the facilities. Commenters explained the patient may be forced to accept an inappropriate device because the right one for them is not available while in a facility resulting in practitioners and caregivers having difficulty in understanding the patient.

Response: In accordance with the statute, we do not establish payment rules for DME based on how the item is furnished in institutional settings, especially in light of the definition of DME in section 1861(n) of the Act, which defines DME as equipment used in a patient’s home.
Comment: One commenter expressed concern that our proposal did not include codes for Accessory for Speech Generating Device, Not Otherwise Classified (HCPCS code E2599) and Accessory for Speech Generating Device, Mounting System (HCPCS code E2512).

Response: We appreciate this comment, but we are not including codes E2599 and E2512 in our list of codes for reclassification at this time because fee schedule amounts for these codes have not been established. When fee schedules are developed, we will review the data for these accessory codes to ensure compliance with the Medicare definition of routinely purchased equipment set forth at 42 CFR §414.220(a). If a change in payment category is required in the future, CMS expects to provide notice via program instructions.

Comment: Some commenters recommended that the low volume of services for SGDs should exempt these codes from our proposal for reclassification from routinely purchased to capped rental. One commenter stated the proposal from CMS reports $20,170,612 in payments for SGDs in 2012 at an average cost of $7,356 for 2,742 services. The commenter also stated this represents .000008 of the United States population utilizing data from the census bureau.

Response: The payment rules at section 1834(a) of the Act do not classify items under the payment classes based on volume of services. As discussed above, the Medicare definition of routinely purchased equipment is set forth at 42 CFR §414.220(a)(2) and specifies that routinely purchased equipment means equipment that was acquired by purchase on a national basis at least 75 percent of the time during the period July 1986 through June 1987. As a result of clarifying and reaffirming this definition, equipment for which claims data did not exist during the 1986/87 period cannot be classified as routinely purchased equipment. This results in such codes being reclassified as capped rental items if they do not fall under any of the other DME payment classes.
Comment: One commenter stated that the pneumatic compression trunk appliance (HCPCS code E0656) and the pneumatic compression chest appliance (HCPCS code E0657), both used in conjunction with pneumatic compression pumps for treatment of lymphedema, are considered routinely purchased because the common diagnosis that allows reimbursement is lymphedema. The commenter states lymphedema is not curable and can only be managed. When a person has been diagnosed with lymphedema and a pneumatic compression pump has been prescribed, it is never for short term use. Thus, the items should not be reclassified from routinely purchased to capped rental payment method.

Response: The payment rules at section 1834(a) of the Act do not classify items under the payment classes based on diagnosis and intended use. As discussed above, the Medicare definition of routinely purchased equipment is set forth at 42 CFR §414.220(a)(2) and specifies that routinely purchased equipment means equipment that was acquired by purchase on a national basis at least 75 percent of the time during the period July 1986 through June 1987. In this final rule, we are reclassifying DME that was not acquired during the period July 1986 through June 1987 or was not acquired by purchase on a national basis at least 75 percent of the time during the period July 1986 through June 1987, and therefore cannot be classified as routinely purchased DME under 42 CFR 414.220(a). This results in certain codes receiving reclassification to capped rental DME if the codes do not fall under any of the other DME payment classes. We do note that only some of the codes in use during July 1986 through June 1987 that describe pneumatic compression appliances for the arm and leg met the definition of routinely purchased equipment. However, the appliances that were not routinely purchased met the definition of inexpensive equipment under §414.220(a)(1). The codes for pneumatic compression appliances for the trunk and chest are considerable more expensive than the
pneumatic compression appliances for the arm and leg and were not acquired on a purchase basis at least 75 percent of the time during July 1986 through June 1987. Payment will therefore made on a capped rental basis for pneumatic compression appliances for the trunk and chest furnished for use with pneumatic compression pumps. Thus, under the capped rental category whether the pneumatic compression chest appliance device is used short term or long term, payment is made in alignment with the number of months for which the equipment was in use, until the beneficiary no longer needs the device or the rental period has ended.

Comment: One commenter requested reclassification of code K0730 controlled dose inhalation drug delivery system from the routinely purchased to the frequently serviced payment category. The commenter also requested CMS reclassify code E0574, which also describes a nebulizer item, to the frequently serviced payment category.

Response: We are not adopting this suggestion to reclassify codes K0730 and E0574 to the frequently serviced payment category. Section 13543 of the Omnibus Budget Reconciliation Act of 1993 (OBRA 93) removed nebulizers from the statutory list of items classified under the frequent and substantial servicing payment class effective with respect to items furnished on or after January 1, 1994. In accordance with these provisions, we continue to believe that these devices should not be classified as items under the payment category for items requiring frequent and substantial servicing under §1834(a)(3)(A) of the Act. As such, we are implementing our proposal to reclassify these codes to the capped rental payment category.

Comment: One commenter opposed reclassification of code E0762 transcutaneous electrical joint stimulation system from the routinely purchased to the capped rental payment category because while significant relief is provided by the system within a short period of time, more significant results are achieved with increased use of the device.
Response: We continue to believe it is appropriate to reclassify code E0762 from the routinely purchased to the capped rental payment category. As discussed above, the Medicare definition of routinely purchased equipment is set forth 42 CFR §414.220(a)(2) and specifies that routinely purchased equipment means equipment that was acquired by purchase on a national basis at least 75 percent of the time during the period July 1986 through June 1987. Therefore, DME, including code E0762, for which claims data did not exist during the 1986/87 period cannot be classified as routinely purchased equipment. This results in such codes being reclassified as capped rental items if they do not fall under any of the other DME payment classes. Furthermore, under the capped rental payment method, the supplier owns the equipment during the rental period and title to the equipment transfers to the beneficiary at the end of a 13th month rental period. Thus, whether the device is used short term or long term, payment is made in alignment with the number of months until the beneficiary no longer needs the device or the rental period has ended.

Comment: One commenter stated jaw motion rehabilitation system from Dynasplint (HCPCS code E1700) should not remain routinely purchased because it was previously billed under a capped rental miscellaneous code and it was assigned by the Medicare Pricing, Data Analysis and Coding (PDAC) contractor to code E1700 which contains other less expensive items.

Response: Since HCPCS code assignment is outside the scope of the proposed rule which only concerns the reclassification of code E1700 from the routinely purchased payment category to the capped rental payment category, and we are not addressing this comment in this final rule.

Comment: Some commenters stated that code E0760 for Osteogenesis Ultrasound Stimulator is not DME but is a therapeutic intervention similar to a drug treatment.
Response: These comments are outside the scope of the proposed rule, and therefore are not addressed in this final rule. The process for reviewing coverage/benefit category for an item is not addressed in this rule. Information on the process can be found at the website http://www.cms.gov/Medicare/Coverage/DeterminationProcess/index.html

Comment: Many commenters raised concerns that code E0760 for Osteogenesis Ultrasound Stimulator remains comparable to electric bone growth stimulators (codes E0747 and E0748) that also treat established nonunion of fractures of long bones and as adjunctive therapy to spinal fusion to improve fusion success rates, which are assigned to the routinely purchased category in accordance with the existing regulatory definition of routinely purchased items. Commenters pointed out the code used to describe osteogenesis stimulators in 1986 through 1987 did not specify the type of stimulator Medicare purchased. Also, commenters noted that code E0760 was initially classified as capped rental DME and reclassified by Medicare to routinely purchased DME based on data from other payers and claims submitted to Medicare.

Response: We recognize the commenters’ concerns and in this final rule, we will revise the list of codes by removing code E0760 from the final list of codes for reclassification to the capped rental DME. We agree that HCPCS codes used to routinely pay for the purchase of osteogenesis stimulators in 1986 and 1987 did not differentiate between types of osteogenesis stimulators and therefore, believe that the general category of osteogenesis stimulator are correctly classified as routinely purchased equipment in accordance with current regulations §414.220(a)(2).

Comment: Commenters noted that the proposed list of HCPCS codes that would be reclassified as capped rental items includes HCPCS codes that describe products cleared by the FDA for single patient use. Commenters stated that reclassifying these devices as capped rental
items goes against their labeling as single patient use devices by the FDA and that some of these devices cannot be cleaned or refurbished for another patient’s use. A commenter noted that a change in payment category could affect various levels of market availability including FDA clearance, product marketing or the company’s business model. Commenters stated a significant investment of resources and time is required to seek a new FDA label to allow these items to be rented to multiple patients. One commenter objected that reclassification would essentially force devices currently labeled for single patient use to be used off-label as rental equipment. Additionally, one commenter recommended that we amend our regulation to provide that all devices cleared by the FDA as class III devices under the Federal Food, Drug, and Cosmetic Act are classified as routinely purchased equipment.

Response: The payment rules under section 1834(a) of the Act do not classify items under the payment classes based on how they are cleared by the FDA. As discussed above, the Medicare definition of routinely purchased equipment under §414.220(a)(2) specifies that routinely purchased equipment means equipment that was acquired by purchase on a national basis at least 75 percent of the time during the period July 1986 through June 1987. As a result of our clarification of this definition, equipment that was not acquired at all during the period July 1986 through June 1987, was not acquired by purchase on a national basis at least 75 percent of the time during the period July 1986 through June 1987, and therefore, cannot be classified as routinely purchased equipment. This results in such codes being reclassified as capped rental items if they do not fall under any of the other DME payment classes. We agree that manufacturers and suppliers of products should be in compliance with FDA requirements, but we do not believe that FDA requirements dictate how items should be classified under sections 1834(a)(2) through (7) of the Act.
After consideration of comments received on the proposed rule and for the reasons we discussed above and in the proposed rule, we are finalizing our proposals and reclassifying certain items identified in this final rule with the exception of code E0760 which will remain classified as routinely purchased equipment. We did not receive comments regarding the effective dates for the reclassifications of these items from the routinely purchased DME category to capped rental DME. For the reasons discussed in the proposed rule (78 FR 40875), we are finalizing the effective dates for the changes of this section in compliance with the required regulatory process as follows:

- April 1, 2014, for items furnished in all areas of the country if the item is not included in Round 2 or Round 1 Recompete CBP;
- July 1, 2016, for items furnished in all areas of the country if the item is included in a Round 2 CBP and not a Round 1 Recompete CBP and for items included in a Round 1 Recompete CBP but furnished in an area other than one of the 9 Round 1 Recompete areas; and
- January 1, 2017, for items included in a Round 1 Recompete CBP and furnished in one of the nine Round 1 Recompete areas.

The April 1, 2014, effective date was selected in order to ensure that these changes do not occur sooner than 60 days after publication of the final rule for claims processing purposes.

V. Clarification of the 3-year Minimum Lifetime Requirement (MLR) for DME

DME is covered by Medicare based, in part, upon section 1832(a) of the Act, which describes the scope of benefits under the supplementary medical insurance program (Medicare Part B), to include “medical and other health services,” which is further defined under section 1861(s) (6) of the Act to include DME. In addition, section 1861(m) (5) of the Act specifically
includes DME in the definition of the term “home health services.” In accordance with section 1861(n) of the Act, the term “durable medical equipment” includes iron lungs, oxygen tents, hospital beds, and wheelchairs used in the patient’s home whether furnished on a rental basis or purchased. The patient’s home includes an institution used as his or her home other than an institution that meets the requirements of section 1861(e)(1) or section 1819(a)(1) of the Act. Besides being subject to this provision, the coverage of DME must meet the requirements of section 1862(a)(1)(A) of the Act, which in general excludes from payment any items or services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and section 1862(a)(6) of the Act, which (except for certain specified exceptions) precludes payment for personal comfort items.

Section 414.202 defines DME as equipment furnished by a supplier or a home health agency that meets the following conditions: (1) can withstand repeated use; (2) effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years; (3) is primarily and customarily used to serve a medical purpose; (4) generally is not useful to an individual in the absence of an illness or injury; and is appropriate for use in the home. Prior to 2012, the definition for DME did not contain a 3-year minimum lifetime requirement (MLR) although Section 110.1 of chapter 15 of the Medicare Benefit Policy Manual (CMS-Pub. 100–02) provided further guidance with regard to the definition of DME and durability of an item that is when an item is considered durable.

A. Current Issues

On November 10, 2011, CMS issued a final rule in which it revised the definition of DME at §414.200 by adding a 3-year MLR effective January 1, 2012, that must be met by an item or device in order to be considered durable for the purpose of classifying the item under the
Medicare benefit category for DME (76 FR 70228 (November 10, 2011)). Specifically, an additional condition under §414.200 is that DME must be equipment furnished by a supplier or a home health agency that, effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years. The change to the regulation was designed to further clarify the meaning of the term “durable” and provide an interpretation of the statute generally consistent with the DME payment and coverage provisions, including, Medicare program guidance at section 280.1 of chapter 1, part 4 of the Medicare National Coverage Determinations Manual (Pub. 100-03) which specifies that an item can withstand repeated use means that the item could normally be rented and used by successive patients. The 3-year MLR is intended to specify that durable equipment is equipment that can withstand repeated use over an extended period of time. Since the vast majority of items covered under the DME benefit over the years last for 3 or more years, the MLR is intended to clarify the scope of the DME benefit primarily for new items coming on the market or in the process of being developed. The standard set forth in regulations gives manufacturers and the public a clear understanding of how long an item would need to withstand repeated use in order to meet the durability requirement for DME. The rule also provides clear guidance to CMS and other stakeholders for making consistent informal benefit category determinations (BCDs) and national coverage determinations (NCDs) for DME.

The 3-year MLR is designed to represent a minimum threshold for a determination of durability for a piece of equipment. The 3-year MLR is not an indication of the typical or average lifespan of DME, which in many cases is far longer than 3 years. The 3-year MLR does not apply to disposable supplies or accessories covered for use with DME such as masks, tubing, and blood glucose test strips. The 3-year MLR is prospective only and does not apply to equipment classified as DME before the regulation was effective, that is, January 1, 2012.
We also determined that the 3-year MLR should not apply to equipment classified as DME before the effective date to allow for continued coverage of such equipment that healthcare industry and beneficiaries have come to rely on, regardless of whether those items met the 3-year MLR set forth at 42 CFR 414.202 (76 FR 70288). Given that reliance, we indicated we did not intend to reopen those prior decisions and reclassify the equipment in light of the 3-year standard. We believe that continuing Medicare coverage for items that qualified as DME prior to the effective date helps avoid disrupting the continuity of care for the beneficiaries that received such items for medical treatment prior to January 1, 2012.

Beneficiaries have been relying on these items for their treatment to the extent that the items have been covered as DME under Medicare. Furthermore, we believed that a vast majority of the categories of items that were classified as DME before January 1, 2012, did function for 3 or more years. We also noted that the 3-year durability rule would only apply to new products, and, to the extent that a modified product is not a new product, the 3-year MLR would not be applicable.

In response to the public comments that requested further clarification on the application of the grandfathering provision for the 3-year MLR, we noted that we would consider issuing additional guidance to provide further clarification, if necessary (76 FR 70290). For purposes of providing additional guidance on the scope of the grandfathered items under the provision, we invited public comments on this issue.

B. Scope of the 3-Year MLR for DME

Under §414.202, effective with respect to items classified as DME after January 1, 2012, an item is not considered durable unless it has an expected life of at least 3 years. Therefore, the 3-year MLR applies to new items after January 1, 2012, and does not apply to items covered
under the DME benefit on or prior to January 1, 2012. Items classified as DME on or before January 1, 2012, are considered “grandfathered items” for the purpose of this requirement, regardless of whether they meet the 3-year rule.

For the purpose of providing further guidance on the scope of the 3-year MLR, in the proposed rule (78 FR 40877), we provided clarification about how we would regard grandfathered items covered as DME prior to the effective date and we requested comments on that clarification. We proposed that if the product is modified (upgraded, refined, reengineered, etc.) after January 1, 2012, the item would still be classified as DME as a grandfathered item unless the modified product now has an expected life that is shorter than the expected lifetime for the item covered as DME prior to January 1, 2012. In this case, we would consider the item, as modified, to be a new item that is subject to the 3-year MLR. For example, equipment covered prior to January 1, 2012, and described by code X has a life of at least 2 years. If, after January 1, 2012, that item is modified such that it is less durable, such that it no longer lasts for the 2 year period, that modification would render the item “new” and it would be subject to the 3-year MLR. Therefore, since the new (modified) product does not last 3 years, it would not meet the definition of DME under the regulation and could not be covered or be billed using the code that described the item before it was modified.

We sought comments on this proposed clarification.

C. Response to Comments on the 3-Year MLR for DME

We received approximately 13 comments on the proposed regulation (78FR 40876-40877) regarding clarification of the grandfathering provision of the 3-year MLR for DME. Commenters included medical device manufacturers, suppliers, advocacy groups and coalitions.
Comment: Most commenters acknowledged and appreciated that CMS proposed the clarification of the grandfathering provision of the 3-year MLR for DME.

Response: We thank the commenters for their input and support. We note that the clarification regarding grandfathered items that are modified relates to the durability of the item under the definition, and in particular, whether the modified item has a shorter useful life than the expected lifetime for the items covered prior to January 1, 2012.

Comment: Two commenters supported our clarification in the proposed rule of the grandfathering provision of the 3-year MLR for DME. The commenters believed that the proposed clarification to continue to cover grandfathered items if modified as long as the modification did not shorten its useful life was reasonable and encouraged CMS to adopt it.

Response: We thank the commenters for their support. However, we wish to clarify that the proposed rule addressed how we would regard grandfathered items covered as DME prior to the effective date. We proposed that if a grandfathered product is modified (upgraded, refined, reengineered, etc.), the item would still be classified as a grandfathered item unless the product has been modified to be less durable, such that it now has an expected life that is shorter than the expected lifetime for the item covered as DME prior to January 1, 2012. In this case, we would consider the item, as modified, to lose its grandfathered status and thus it would be treated as a new item that is subject to the 3-year MLR.

Comment: Several commenters indicated that the proposed rule still leaves great uncertainty regarding which modifications will result in products that continue to be, or are no longer, grandfathered. Without specific vignettes or parameters that illustrate how CMS will
address these matters when certain new products come onto the market, the guidance in the proposed rule will not resolve the questions that remain. Specifically,

1. If application of new technology renders a product more effective but reduces its minimum lifetime; will the 3-year requirement be applied?

2. It does not provide further details regarding the extent of changes that could be made to an existing DME product such that it would still be subject to grandfathering provision.

3. Must a modified item fall within the same HCPCS code and/or DME product category as a grandfathered item in order for it to also fall within the grandfathering provision and not be considered a new item?

4. If a modification of an existing product results in the designation of another HCPCS code; will this trigger the 3-year requirement?

Response: We thank the commenters for their input. As noted in the final rule (76 FR 70289, 70290 (November 10, 2011)), the 3-year MLR for DME is applied on a prospective basis. That is, the 3-year MLR only applies to new items, meaning items that were not covered as DME on or prior to January 1, 2012. We clarified in the proposed rule (78 FR 40877) that items paid for as DME on or before January 1, 2012, are considered “grandfathered items” for the purpose of the 3-year MLR for DME, regardless of whether they meet the 3-year rule. If a grandfathered item is modified (upgraded, refined, reengineered, etc.) after January 1, 2012, the item would still be considered a grandfathered item unless the item has been modified to be less durable, such that it now has an expected life that is shorter than the lifetime for the grandfathered item, which was covered as DME on or prior to January 1, 2012. Therefore, if application of new
technology renders a product more effective but reduces its durability; then the product would lose its grandfathered status and the 3-year requirement would apply.

The change we made to the regulation to establish a 3-year MLR for DME was designed to further clarify the meaning of the term “durable.” Based on our experience with the Medicare program, the vast majority of items covered as DME last for 3 years or longer; however, the purpose of the grandfathering provision is to ensure continued coverage for the items that were paid as DME before the effective date of the MLR requirement and, to avoid disruption of the continuity of care for the beneficiaries using such equipment. In response to the specific concerns of the commenters, the parameters of the grandfathering provision are:

1. An item paid for as DME on or before January 1, 2012, is considered a grandfathered item for the purpose of the 3-year MLR for DME, regardless of whether they meet the 3-year rule; and

2. A grandfathered item that is modified (upgraded, refined, reengineered, etc.), is still considered a grandfathered item rather than a new item unless the item is less durable, such that it now has an expected life that is shorter than the expected lifetime for the item covered as DME on or prior to January 1, 2012.

Making individual determinations about whether a modified version of an item that was paid as DME on or prior to January 1, 2012, lasts as long as the item that was paid as DME on or prior to January 1, 2012, involves a case-by-case review of the relevant facts. Therefore, specific vignettes or parameters that illustrate how CMS will make these individual determinations could be misleading since it is not possible to illustrate every possible scenario addressing various items paid for as DME in the past and how they could be modified in the future. With regard to comments regarding HCPCS codes, there are a variety of coding changes. A code could be
added for a completely new category of items that have never been paid for by Medicare and therefore these items would be subject to the 3-year MLR. Alternatively, a new code could be the result of a coding action whereby existing codes are revised to form a new code or codes. In these cases, the determination regarding whether an item is a grandfathered item not subject to the 3-year MLR will depend on whether the item was paid for as DME on or prior to January 1, 2012, under codes in effect on or prior to January 1, 2012.

Comment: Some commenters stated that the proposed rule does not provide clarity on what is a completely “new product” that would never be subject to the grandfathering provision.

Response: A new product is a product that was not paid for as DME on or prior to January 1, 2012, or a grandfathered item that loses its grandfathered status.

Comment: Some commenters indicated that it is unclear what would be considered a modified product that would be subject to the grandfathering provision provided that the modifications do not result in a reduced minimum lifetime of the product. Would a premarket approval product approved after January 1, 2012, that is similar in structure and function to grandfathered products be considered a modified version of the grandfathered products? Is newly cleared 510(k) product considered to be a modified version of the predicate device? It is unclear whether a new product cleared by the FDA through the Premarket Approval (PMA) process as opposed to a PMA supplement approved after January 1, 2012, can be considered to be a modification of a grandfathered product or whether a new product cleared by the FDA through the 510(k) process as substantially equivalent to other, previously cleared, predicate products is considered to be a modification of a predicate device.
**Response:** A grandfathered product is a specific product (make, manufacturer, model, model number, etc.) that was covered and paid for as DME on or prior to January 1, 2012. Any product that is not a grandfathered product or a grandfathered product that is modified so that it is less durable, such that it now has an expected lifetime that is shorter than the expected lifetime of the product covered as DME on or prior to January 1, 2012, is subject to the 3-year MLR. CMS will continue to consider these issues and provide additional guidance if necessary.

**Comment:** Several commenters voiced concerns that the final rule will serve as a major deterrent to future investments in new technologies. There may be desirable innovations made to a grandfathered product that would reduce the minimum lifetime of the product. If changes to a product that result in a different HCPCS code assignment or DME product category by definition do not fall within the grandfathering provision then manufacturers do not have the incentive to research and develop a grandfathered product’s safety and effectiveness in treating. By eliminating reimbursement under Medicare DME benefit for modified grandfathered products containing innovations that are clinically beneficial to the patients but may reduce the minimum lifetime of those products, the proposed clarification discourages innovation of existing technologies.

**Response:** We believe that the 3-year MLR to clarify the term durable and the grandfathering provision are reasonable given the 5 year reasonable lifetime requirement, general DME payment rules and industry standards which support the fact that DME items should be able to withstand repeated use. We do not believe the rule is a deterrent. The rule is designed to clarify the grandfathering provision and ensure that such products are not modified to be less durable.

Based upon our experience with the Medicare program, the vast majority of items covered as DME last for 3 years or longer. The purpose of the grandfathering provision is to
continue the Medicare coverage for the items that were paid as DME on or prior to the effective date, in order to avoid disruption of the continuity of care for the beneficiaries that had received items for medical treatment on or prior to January 1, 2012.

Comment: A few commenters suggested that instead of using the MLR to determine whether modified DME is a “new” device, CMS should focus on whether the modified device has the same clinical application as the grandfathered DME. This criterion would be a better measure of whether the device is “new” than whether it meets what a few commenters characterized as an arbitrary MLR rule. CMS should instead establish reasonable parameters under which products should be considered comparable to existing DME products in order to be subject to the grandfathering provision—any modification, upgrade, redesign, improvement or new indication of an existing DME product that maintains the product’s core clinical technology or mechanism of action should be eligible for reimbursement under the DME benefit category.

Response: We thank the commenters for their input. However, our proposal regarding the 3-year MLR with regard to the definition of DME was to clarify the issue of durability as it relates to grandfathering status. Our proposal centered on the lifetime of the product as a result modification (upgraded, refined, reengineered, etc.). We do not believe that issues such as core clinical technology or clinical application to determine whether a modified grandfathered item is a new DME as suggested by the commenters, speaks to the issue of durability with regard to our interpretation of the statutory DME provisions.

Comment: A few commenters expressed concerns that the proposed rule will require manufacturers to undertake expensive testing to demonstrate that their equipment continues to qualify under the grandfathering provision. They questioned whether there is a benchmark for deciding whether the modified device has an MLR that is shorter than the grandfathered device.
(e.g., is it an MLR that is a year shorter, 90 days shorter, or a day shorter than that of the grandfathered DME?). Commenters believe that, instead of providing clarity, CMS has injected even more subjectivity and ambiguity into the Medicare coverage and coding process and provides virtually no guidance when the minimum lifetime of a modified device does not conclusively meet the 3-year threshold. Commenters stated that, in the past, CMS has stated that it will base these decisions on a review of existing data, but the outcome in these cases ultimately will hinge on subjective interpretation of the data. The commenters note that this type of analysis will be useless in assessing new technologies, which typically are not included in independent comparative studies of the type CMS has said it plans to consult.

Response: We thank the commenters for their input but do not believe that the proposed regulation injects subjectivity and ambiguity into the Medicare coverage and coding process. We are not proposing a new process to determine whether a modified device has an expected life that is shorter than the original grandfathered device; therefore, no new types of tests are needed to make determinations regarding the expected lifetime of products. As discussed previously, we will continue to follow the current BCD process to determine on an individual consideration basis if a modified grandfathered item falls within the grandfathering provision. We will review information and evidence, which a supplier/manufacturer may submit, consistent with the current BCD process to determine the expected life of the equipment. As discussed previously, the BCD process typically involves reviewing information from various sources including but not limited to information related to FDA pre-market clearance, product manuals, operating guides, warranty documents, and standardized test results. The NCD process is available at http://www.cms.gov/DeterminationProcess/Downloads/FR09262003.pdf. See also, 68 FR 55638 (September 23, 2003). Additionally, we routinely collect information regarding durability of
new products as part of the HCPCS editorial process in order to identify categories of new DME subject to the procedures established in accordance with the mandate of section 531(b) of the Medicare, Medicaid and SCHIP Benefit Improvement and Protection Act of 2000 (BIPA 2000), Public Law 106–554. Based on our experience with the program, this information has been readily available from the manufacturers of these items and other entities submitting requests for changes to the HCPCS. Information on the HCPCS Level II coding process is available at: http://www.cms.gov/MedHCPCSGenInfo/Downloads/2013_HCPCS_Application.pdf and http://www.cms.gov/MedHCPCSGenInfo/08_HCPCSPublicMeetings.asp#TopOfPage.

Comment: Some commenters argued that in this case, CMS’ original concern about disrupting patient care continues to hold true. Commenters claim that the proposal to modify the grandfathering provision of §414.202 will disrupt the care of beneficiaries using the grandfathered DME. Beneficiaries who have been using the grandfathered DME will no longer have Medicare coverage for the medically necessary device they depend on. Physicians and other practitioners will be unable to order devices that have been proven therapeutically effective for the patients they treat. For these beneficiaries and providers, it will almost certainly be true that they will be left without an equally effective alternative for continuing their care.

Response: We thank the commenters for their input, but we do not agree with the above comment. We note that the proposed rule was designed to clarify the grandfathering provision. The proposed clarification of the grandfathering provision is designed to address how grandfathered products could be modified without losing their grandfathered status. The commenters concerns that beneficiaries who have been using the grandfathered DME will no longer have Medicare coverage for the medically necessary device they depend on or that physicians will be unable to order devices that have been proven therapeutically effective for the
patients are inaccurate. On the contrary, the purpose of the grandfathering provision for the 3-
year MLR was to continue Medicare coverage for items that were classified as DME on or prior
to the effective date, in order to avoid disruption of the continuity of care for the beneficiaries
that had already received these items for medical treatment. For the reasons stated above, we do
not believe that the clarification of the grandfathering provision will disrupt the continuing care
for beneficiaries that are using the grandfathered DME.

Comment: Some commenters urged CMS to convene a study panel to allow stakeholders
to collaborate with the agency to examine a few central questions such as whether a modified
item must fall within the same HCPCS code and/or DME product category as a grandfathered
item in order for it to also fall within the grandfathering provision. Commenters asked CMS to
consider convening a stakeholder meeting to solicit views from patients, healthcare providers,
DME manufacturers and other health policy experts.

Response: We appreciate the comment. We established the 3-year MLR effective with
respect to items classified as DME on or after January 1, 2012, via notice and comment
rulemaking. We are clarifying the grandfathering provision for the 3-year MLR via notice and
comment rulemaking. In addition, we will continue to follow the current processes including
BCD, NCD, Local Coverage Determinations (LCD), and HCPCS codes to implement the 3-year
MLR and the grandfathering provision. These processes include meetings with manufacturers in
addition to the public where we seek input from the stakeholders. We will continue to receive
input from stakeholders consistent with the BCD and NCD process when applying the 3-year
MLR and the grandfathering provision. See 68 FR 55634 (September 26, 2003); and http://www.
Cms.gov/Determination Process/Downloads/FR09262003.pdf. See also, information on the
HCPCS Level II coding process at:
http://www.cms.gov/MedHCPCSGenInfo/08_HCPCSPublicMeetings.asp#TopOfPage.

Comment: Some commenters stated that as other payers follow Medicare guidelines, it is important to revise ill-conceived Medicare policy now before regulations that harm people with disabilities and chronic conditions are replicated at the State level.

Response: This comment is outside the scope of the proposed rule.

Comment: One commenter stated that CMS proposes to clarify the scope and application of the MLR “grandfathering” provision by stipulating that products will lose the grandfather status if the modified product will have an expected life that is shorter than three years. In other words, the commenter believes the proposed rule would result in non-coverage of any grandfathered item that is modified.

Response: We thank the commenter for the input. However, the statement in the above comment that a modified product that has an expected life that is shorter than three years will no longer be grandfathered and therefore, lose coverage status is inaccurate. We proposed that a product covered as DME prior to 2012 that is modified would still be grandfathered as long as the expected lifetime of the product is equal to or greater than the lifetime of the product covered prior to 2012. Under this proposal, if the product lost grandfathered status (because the modification reduced the expected lifetime of the product covered prior to 2012), the product would be subject to the 3-year MLR. The application of 3-year MLR would determine whether product would be otherwise covered under the definition. For grandfathered items that have a lifetime shorter than 3-years, modifications that reduce such lifetime generally would result in the product no longer meeting the definition given the application of the 3-year MLR (because the grandfathered status was lost). However, for grandfathered products that have a lifetime
greater than 3 years, modifications that shorten such lifetime may or may not result in non-coverage under the definition when the 3-year MLR is applied. For example, if a grandfathered product covered as DME prior to 2012 with a lifetime of four years is modified, resulting in a product with a lifetime of two and a half years (and thereby losing grandfathering status), the product would no longer meet the definition of DME, because the 3-year MLR is not met given that the lifetime of the modified product is less than three years. In the same example, if the modification resulted in a reduced lifetime of the product to 3.5 years, the product, even though it lost grandfathering status, would satisfy the 3-year rule, and continue meet the definition of DME.

After consideration of comments received on the proposed rule, we are finalizing the clarification of the grandfathering provision of the 3-year MLR for DME. The 3-year MLR applies, effective January 1, 2012, but does not apply to items covered under the DME benefit on or prior to January 1, 2012 (“grandfathered items”). However, effective April 1, 2014, if the grandfathered item is modified (upgraded, refined, reengineered, etc.), and the modified item now has an expected life that is shorter than the expected lifetime for the item covered as DME prior to January 1, 2012, the modified item will lose grandfathered status. In this case, we would consider the item, as modified, to be a new item that is subject to the 3-year MLR.

VI. Implementation of Budget-Neutral Fee Schedules for Splints, Casts and Intraocular Lenses (IOLs)

A. Background

1. Payment under Reasonable Charges

   Payment for most items and services furnished under Part B of the Medicare program is made through contractors known as Medicare Administrative Contractors (MACs). These