in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. et seq.). Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:


2. In § 180.910, add alphabetically the inert ingredients to the table to read as follows:

§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

<table>
<thead>
<tr>
<th>Inert ingredients</th>
<th>Limits</th>
<th>Uses</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethyl 9-decanamide (CAS Reg. No. 1356964–77–6).</td>
<td>Not to exceed 20% by weight of pesticide formulation</td>
<td>Surfactant, solvent</td>
</tr>
<tr>
<td>N,N-Dimethyldecanamide (CAS Reg. No. 3007–53–2)</td>
<td>Not to exceed 20% by weight of pesticide formulation</td>
<td>Surfactant, solvent</td>
</tr>
<tr>
<td>N,N-Dimethyltetradecanamide (CAS Reg. No. 3015–65–4).</td>
<td>Not to exceed 20% by weight of pesticide formulation</td>
<td>Surfactant, solvent</td>
</tr>
</tbody>
</table>

[FR Doc. 2018–06108 Filed 3–29–18; 8:45 am]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 414

[CMS–6078–N]

Medicare Program; Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Items; Update to the Master List of Items Frequently Subject to Unnecessary Utilization

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Master list deletions.

SUMMARY: This document announces the deletion of four Healthcare Common Procedure Coding System (HCPCS) codes from the Master List of Items Frequently Subject to Unnecessary Utilization that could be potentially subject to Prior Authorization as a condition of payment.

DATES: This action is applicable on April 30, 2018.


SUPPLEMENTARY INFORMATION:

I. Background

In the December 30, 2015 final rule (80 FR 81674) titled “Medicare Program; Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies,” we implemented section 1834(a)(15) of the Social Security Act (the Act) by establishing an initial Master List (called the Master List of Items Frequently Subject to Unnecessary Utilization) of certain DMEPOS that the Secretary determined, on the basis of prior payment experience, are frequently subject to unnecessary utilization and by establishing a prior authorization process for these items. The Master List includes items that meet the following criteria:

• Appear on the DMEPOS Fee Schedule list.
• Have an average purchase fee of $1,000 or greater (adjusted annually for inflation) or an average monthly rental fee schedule of $100 or greater (adjusted annually for inflation). (These dollar amounts are referred to as ‘‘the payment threshold’’.)
• Meet either of the following criteria:
  ++ Identified in a Government Accountability Office (GAO) or Department of Health and Human Services Office of Inspector General (OIG) report that is national in scope and published in 2007 or later as having a high rate of fraud or unnecessary utilization.
  ++ Listed in the 2011 or later Comprehensive Error Rate Testing (CERT) program’s Annual Medicare Fee-For-Service (FFS) Improper Payment Rate Report DME and/or DMEPOS Service Specific Report(s).

The rule described the maintenance process of the Master List as follows:

• The Master List is self-updating annually. That is, items on the DMEPOS Fee Schedule that meet the “payment threshold” are added to the list when
the item is listed in a future OIG or GAO report of a national scope or listed in a future CERT DME and/or DMEPOS Service Specific Report(s).

- Items remain on the Master List for 10 years from the date the item was added to the Master List.
- Items are updated on the Master List when the Healthcare Common Procedure Coding System (HCPCS) codes representing an item have been discontinued and crosswalked to an equivalent item.
- Items are removed from the list sooner than 10 years if the purchase amount drops below the “payment threshold”.
- Items that age off the Master List because they have been on the list for 10 years can remain on or be added back to the Master List if a subsequent OIG or CERT DME and/or DMEPOS Service Specific Report(s) identifies the item to be frequently subject to unnecessary utilization.
- Items already on the Master List that are identified by a GAO/OIG, or CERT DME and/or DMEPOS Service Specific Report(s) will remain on the list for 10 years from the publication date of the new report(s).
- We will notify the public annually of any additions and deletions from the Master List by posting the notification in the Federal Register and on the CMS Prior Authorization website.

II. Provisions of the Document

In the December 30, 2015 final rule (80 FR 81674), we stated that we would notify the public annually of any additions and deletions from the Master List by posting the notification in the Federal Register and on the CMS Prior Authorization website.

III. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements.

The full updated list is also available in the download section of the following CMS website: https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/DMEPOS/Prior-Authorization-Process-for-Certain-Durable-Medical-Equipment-Prosthetic-Orthotics-Supplies-Items.html.

IV. Regulatory Impact Statement


Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety

<table>
<thead>
<tr>
<th>HCPCS</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E0260</td>
<td>Hospital bed semi-electric (head and foot adjustment) with any type side rails with mattress.</td>
</tr>
<tr>
<td>E0601</td>
<td>Continuous Airway Pressure (CPAP) Device.</td>
</tr>
<tr>
<td>E1390</td>
<td>Oxygen Concentrator.</td>
</tr>
<tr>
<td>K0004</td>
<td>High strength, lightweight wheelchair.</td>
</tr>
</tbody>
</table>

Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).
effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This document does not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.5 million to $38.5 million in any 1 year. Individuals and states are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this document will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this action will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. Currently, that threshold is approximately $148 million. This action will have no consequential effect on state, local, or tribal governments or on the private sector.

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017 and requires that the costs associated with significant new regulations “shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.” OMB’s interim guidance, issued on April 5, 2017, https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2017/M-17-21-OMB.pdf, explains that for Fiscal Year 2017 the above requirements only apply to each new “significant regulatory action that imposes costs.” It has been determined that this document is not a “significant regulatory action” and thus does not trigger the aforementioned requirements of Executive Order 13771.

In accordance with the provisions of Executive Order 12866, this document was reviewed by the Office of Management and Budget.


Seema Verma,
Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2018–06552 Filed 3–29–18; 8:45 am]