J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

This action does not establish an environmental health or safety standard, and is therefore not is not subject to environmental justice considerations under Executive Order 12898 (59 FR 7629, February 16, 1994), because it does not establish an environmental health or safety standard. This regulatory action is a procedural change and does not have any impact on human health or the environment.

K. Congressional Review Act (CRA)

This rule is exempt from the CRA (5 U.S.C. 801 *et seq.*) because it is a rule of agency organization, procedure or practice that does not substantially affect the rights or obligations of non-agency parties.

List of Subjects in 40 CFR Part 750

Administrative practice and procedure, Chemicals, Environmental protection, Hazardous substances.

Dated: December 8, 2016.

Gina McCarthy,

Administrator.

Therefore, 40 CFR chapter I is amended as follows:

PART 750—PROCEDURES FOR RULEMAKING UNDER SECTION 6 OF THE TOXIC SUBSTANCES CONTROL ACT [AMENDED]

■ 1. The authority citation for part 750 continues to read as follows:

Authority: 15 U.S.C. 2605.

Subpart A—[Removed and Reserved]

■ 2. Subpart A, consisting of §§ 750.1 through 750.9 and an appendix, is removed and reserved.

■ 3. Revise § 750.10 to read as follows:

§ 750.10 Applicability

Sections 750.10–750.15 apply to all rulemakings under authority of section 6(e)(3)(B) of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2605(e)(3)(B) with respect to petitions filed pursuant to § 750.11(a).

■ 4. Revise § 750.13 to read as follows:

§ 750.13 Notice of proposed rulemaking.

Rulemaking for PCB exemptions filed pursuant to § 750.11(a) shall begin with the publication of a notice of proposed rulemaking in the **Federal Register**. The notice shall state in summary form the required information described in § 750.11(c). Due to time constraints, the notice need not indicate what action EPA proposes to take on the exemption petitions.

§§ 750.14 and 750.15 [Removed]

■ 5. Remove §§ 750.14 and 750.15.

§ 750.16 [Redesignated as § 750.14]

■ 6. Redesignate § 750.16 as § 750.14.

§§ 750.17 through 750.20 [Removed]

■ 7. Remove §§ 750.17 through 750.20.

§§ 750.21 [Redesignated as § 750.15]

■ 8. Redesignate § 750.21 as § 750.15, and revise it to read as follows:

§ 750.15 Final rule.

(a) [Reserved]

(b) EPA will grant or deny petitions under TSCA section 6(e)(3)(B) submitted pursuant to § 750.11.

(c) In determining whether to grant an exemption to the PCB ban, the Agency shall apply the two standards enunciated in TSCA section 6(e)(3)(B).

■ 9. Revise § 750.30 to read as follows:

§ 750.30 Applicability

Sections 750.30 through 750.35 apply to all rulemakings under authority of section 6(e)(3)(B) of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2605(e)(3)(B) with respect to petitions for PCB processing and distribution in commerce exemptions filed pursuant to § 750.31(a).

■ 10. Revise § 750.33 to read as follows:

§ 750.33 Notice of proposed rulemaking.

Rulemaking for PCB exemptions filed pursuant to § 750.31(a) shall begin with the publication of a notice of proposed rulemaking in the **Federal Register**. The notice shall state in summary form the required information described in § 750.31(c).

§§ 750.34 and 750.35 [Removed]

■ 11. Remove §§ 750.34 and 750.35.

§ 750.36 [Redesignated as § 750.34]

■ 12. Redesignate § 750.36 as § 750.34.

§§ 750.37 through 750.40 [Removed]

■ 13. Remove §§ 750.37 through 750.40.

§ 750.41 [Redesignated as § 750.35]

■ 14. Redesignate § 750.41 as § 750.35, and revise it to read as follows:

§ 750.35 Final rule.

(a) [Reserved]

(b) EPA will grant or deny petitions under TSCA section 6(e)(3)(B) submitted pursuant to § 750.31.

(c) In determining whether to grant an exemption to the PCB ban, EPA will apply the two standards enunciated in TSCA section 6(e)(3)(B).

[FR Doc. 2016–30055 Filed 12–20–16; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 414

[CMS–6072–N]

Medicare Program; Implementation of Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Items and Publication of the Initial Required Prior Authorization List of DMEPOS Items That Require Prior Authorization as a Condition of Payment

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

ACTION: Implementation of list and phases.

SUMMARY: This document announces the implementation of the prior authorization program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items in two phases and the issuance of the initial Required Prior Authorization List of DMEPOS items that require prior authorization as a condition of payment.

DATES: Phase one of implementation is effective on March 20, 2017. Phase two of implementation is effective on July 17, 2017.

FOR FURTHER INFORMATION CONTACT: Jennifer Phillips, (410) 786–1023. Linda O'Hara (410) 786–8347. Scott Lawrence (410) 786–4313.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 1832, 1834, and 1861 of the Social Security Act (the Act) establish that the provision of durable medical equipment, prosthetic, orthotics, and supplies (DMEPOS) is a covered benefit under Part B of the Medicare program.

Section 1834(a)(15) of the Act authorizes the Secretary to develop and periodically update a list of DMEPOS items that the Secretary determines, on the basis of prior payment experience, are frequently subject to unnecessary utilization and to develop a prior authorization process for these items.

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 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 is self-updating annually, and items remain on the Master List for 10 years from the date the item was added to the Master List. Items are removed from the list sooner than 10 years if the purchase amount drops below the payment threshold described later in this section. 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 Web site. 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 and/or the Supplementary Appendices for the Medicare Fee-for-Service Improper Payments Report.

II. Provisions of the Document

In the December 30, 2015 final rule (80 FR 81689), we stated that we would inform the public of those DMEPOS items on the Required Prior Authorization List in the **Federal Register** with 60-day notice before implementation. The Required Prior Authorization List specified in § 414.234(c)(1) is selected from the Master List of Items Frequently Subject to Unnecessary Utilization (as described in § 414.234(b)(1)), and items on the Required Prior Authorization List require prior authorization as a condition of payment. Additionally, we stated that CMS may elect to limit the prior authorization requirement to a particular region of the country if claims data analysis shows that unnecessary utilization of the selected item(s) is concentrated in a particular region. The purpose of this document is to inform the public that we are implementing the prior authorization program for certain DMEPOS items and to provide the initial Required Prior Authorization List of DMEPOS items that require prior authorization as a condition of payment. To assist stakeholders in preparing for implementation of the prior authorization program, CMS is providing 90 days' notice.

The following two DMEPOS items, represented by HCPCS (Healthcare Common Procedure Coding System) codes K0856 and K0861 are added to the Required Prior Authorization List:

- K0856 HCPCS: Power wheelchair, group 3 standard, single power option, sling/solid seat/back, patient weight capacity up to and including 300 pounds.
- K0861 HCPCS: Power wheelchair, group 3 standard, multiple power option, sling/solid seat/back, patient weight capacity up to and including 300 pounds.

Power wheelchairs, represented by HCPCS codes K0856 and K0861, will be subject to the requirements of the prior authorization program for certain DMEPOS items as outlined in § 414.234. (We note that these Group 3 power wheelchairs are not part of the separate Prior Authorization of Power Mobility Devices (PMDs) Demonstration.)

We will implement a national prior authorization program for K0856 and K0861 in two phases, as specified in the **DATES** section of this document. We are implementing the program in this manner to test the new prior authorization program because new complex claims processing systems changes are required for implementation. This phased-in approach will allow us to identify and resolve any unforeseen issues by using a smaller claim volume in phase one before national implementation occurs in phase two.

In phase one of implementation, which begins as specified in the **DATES** section of this document, we will limit the prior authorization requirement to one state in each of the four DME Medicare Administrative Contractors (MAC) geographic jurisdictions, as follows: Illinois, Missouri, New York, and West Virginia. Initially limiting the program to one state in each of the DME MAC geographic jurisdictions allows us to test the national claims processing system and the local DME MAC processes. In phase two, which begins as specified in the **DATES** section of this document, we will expand the program to the remaining states.

Prior to furnishing the item to the beneficiary and prior to submitting the claim for processing, a requester must submit a prior authorization request that includes evidence that the item complies with all applicable Medicare coverage, coding, and payment rules. Consistent with § 414.234(d), such evidence must include the order, relevant information from the beneficiary's medical record, and relevant supplier-produced documentation. After receipt of all applicable required Medicare documentation, CMS or one of its review contractors will conduct a medical review and communicate a decision that provisionally affirms or non-affirms the request.

We will issue specific prior authorization guidance in subregulatory communications, including final timelines, which are customized for the DMEPOS item subject to prior authorization, for communicating a provisionally affirmed or non-affirmed decision to the requester. In the December 30, 2015 final rule, we stated that this approach to final timelines provides flexibility to develop a process that involves fewer days, as may be appropriate, and allows us to safeguard beneficiary access to care. If at any time we become aware that the prior authorization process is creating barriers to care, we can suspend the program.

III. Collection of Information Requirements

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

Dated: December 1, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2016–30273 Filed 12–19–16; 4:15 pm]

BILLING CODE 4120–01–P