not likely to have an economically significant impact.

Specifically, the RIA for the 2017 Rule stated that, ''[. . .] manufacturers are required to ensure they do not overcharge covered entities, and a civil monetary penalty could result from overcharging if it met the standards in this final rule. HHS envisions using these penalties in rare situations. Since the Program's inception, issues related to overcharges have been resolved between a manufacturer and a covered entity and any issues have generally been due to technical errors in the calculation. For the penalties to be used as defined in the statute and in this [2017] rule, the manufacturer overcharge would have to be the result of a knowing and intentional act. Based on anecdotal information received from covered entities, HHS anticipates that this would occur very rarely if at all.'' Since the civil penalties envisioned in the 2017 Rule were expected to be rare, delay of these civil penalties is unlikely to have an economically significant impact.

Additionally, the 2017 Rule codified the practice of manufacturers charging $0.01 for drugs with a ceiling price below $0.01, which the 2017 Rule RIA described as ''[. . .] a long-standing HRSA policy, and HRSA believes the majority of manufacturers currently follow the practice of charging $0.01.'' Delay of this rule will delay the codification of this practice, but since it is already a longstanding policy and widespread practice, the impact of delay is not likely to be economically significant.

Executive Order 13771, titled ''Reducing Regulation and Controlling Regulatory Costs,'' was issued on January 30, 2017. This rule is not subject to the requirements of E.O. 13771 because this rule results in no more than *de minimis* costs.

The Regulatory Flexibility Act (RFA)

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) and the Small Business Regulatory Enforcement and Fairness Act of 1996, which amended the RFA, require HHS to analyze options for regulatory relief of small businesses. If a rule has a significant economic effect on a substantial number of small entities, the Secretary must specifically consider the economic effect of the rule on small entities and analyze regulatory options that could lessen the impact of the rule. HHS will use an RFA threshold of at least a 3 percent impact on at least 5 percent of small entities.

For purposes of the RFA, HHS considers all health care providers to be small entities either by meeting the Small Business Administration (SBA) size standard for a small business, or by being a nonprofit organization that is not dominant in its market. The current SBA size standard for health care providers ranges from annual receipts of $7 million to $35.5 million. As of January 1, 2018, over 12,800 covered entities participate in the 340B Program, which represent safety-net health care providers across the country.

In addition, the rule would affect drug manufacturers (North American Industry Classification System code 325412: Pharmaceutical Preparation Manufacturing). The small business size standard for drug manufacturers is 750 employees. Approximately 600 drug manufacturers participate in the 340B Program. While it is possible to estimate the impact of the rule on the industry as a whole, the data necessary to project changes for specific or groups of manufacturers is not available, as HRSA does not collect the information necessary to assess the size of an individual manufacturer that participates in the 340B Program. HHS has determined, and the Secretary certifies that this final rule will not have a significant impact on the operations of a substantial number of small manufacturers; therefore, we are not preparing an analysis of impact for this RFA. HHS estimates that the economic impact on small entities and small manufacturers will be minimal.

Unfunded Mandates Reform Act

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year.'' In 2017, that threshold is approximately $148 million. HHS does not expect this rule to exceed the threshold.

Executive Order 13132—Federalism

HHS has reviewed this final rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have ''federalism implications.'' This final rule would not ''have substantial direct effects on the States, or on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that OMB approve all collections of information by a federal agency from the public before they can be implemented. This final rule is projected to have no impact on current reporting and recordkeeping burden for manufacturers under the 340B Program. This final rule would result in no new reporting burdens.

Dated: May 30, 2018.

George Sigounas

Administrator, Health Resources and Services Administration.

Approved: May 31, 2018.

Alex M. Azar II

Secretary, Department of Health and Human Services.

[FR Doc. 2018–12103 Filed 6–1–18; 11:15 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 414

[CMS–6080–N]

Medicare Program; Update to the Required Prior Authorization List of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Items That Require Prior Authorization as a Condition of Payment

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

ACTION: Update to list.

SUMMARY: This document announces the addition of 31 Healthcare Common Procedure Coding System (HCPCS) codes to the Required Prior Authorization List of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Items that require prior authorization as a condition of payment. Prior authorization for these codes will be implemented nationwide.

DATES: Implementation is effective on September 1, 2018.

FOR FURTHER INFORMATION CONTACT:
Emily Calvert, (410) 786–4277.
Andre Damonze, (410) 786–1795.

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. In the same final rule, we also 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.

In addition to the prior authorization process for certain DMEPOS items that we established under section 1834(a)(15) of the Act, on September 1, 2012, we implemented the Medicare Prior Authorization for Power Mobility Devices (PMDs) Demonstration that would operate for a period of 3 years (September 1, 2012 through August 31, 2015). This demonstration was established under section 402(a)(1)(J) of the Social Security Amendments of 1967 (42 U.S.C. 1395b–1(a)(1)(J)), which authorizes the Secretary to conduct demonstrations designed to develop or demonstrate improved methods for the investigation and prosecution of fraud in the provision of care or services provided under the Medicare program. The demonstration was initially implemented in California, Florida, Illinois, Michigan, New York, North Carolina, and Texas. These states were selected for the demonstration based upon their history of having high levels of improper payments and incidents of fraud related to PMDs. On October 1, 2014, we expanded the demonstration to 12 additional states (Pennsylvania, Ohio, Louisiana, Missouri, Washington, New Jersey, Maryland, Indiana, Kentucky, Georgia, Tennessee, and Arizona) that have high expenditures and improper payments for PMDs based on 2012 billing data. On July 15, 2015, we announced we were extending the demonstration for 3 years, through August 31, 2018.

II. Provisions of the Document

The purpose of this document is to inform the public that we are updating the Required Prior Authorization List of DMEPOS items that require prior authorization as a condition of payment to include all of the power mobility devices that are part of the PMD demonstration, which are also included on the Master List of Items Frequently Subject to Unnecessary Utilization. To assist stakeholders in preparing for implementation of the prior authorization program, CMS is providing 90 days' notice.

The following 31 DMEPOS items are being added to the Required Prior Authorization List:

HCPCS code	Description
K0813	Power wheelchair, group 1 standard, portable, sling/solid seat and back, patient weight capacity up to and including 300 pounds.
K0814	Power wheelchair, group 1 standard, portable, captains chair, patient weight capacity up to and including 300 pounds.
K0815	Power wheelchair, group 1 standard, sling/solid seat and back, patient weight capacity up to and including 300 pounds.
K0816	Power wheelchair, group 1 standard, captains chair, patient weight capacity up to and including 300 pounds.
K0820	Power wheelchair, group 2 standard, portable, sling/solid seat/back, patient weight capacity up to and including 300 pounds.
K0821	Power wheelchair, group 2 standard, portable, captains chair, patient weight capacity up to and including 300 pounds.
K0822	Power wheelchair, group 2 standard, sling/solid seat/back, patient weight capacity up to and including 300 pounds.
K0823	Power wheelchair, group 2 standard, captains chair, patient weight capacity up to and including 300 pounds.
K0824	Power wheelchair, group 2 heavy duty, sling/solid seat/back, patient weight capacity 301 to 450 pounds.
K0825	Power wheelchair, group 2 heavy duty, captains chair, patient weight capacity 301 to 450 pounds.
K0826	Power wheelchair, group 2 very heavy duty, sling/solid seat/back, patient weight capacity 451 to 600 pounds.
K0827	Power wheelchair, group 2 very heavy duty, captains chair, patient weight capacity 451 to 600 pounds.
K0828	Power wheelchair, group 2 extra heavy duty, sling/solid seat/back, patient weight capacity 601 pounds or more.
K0829	Power wheelchair, group 2 extra heavy duty, captains chair, patient weight 601 pounds or more.
K0835	Power wheelchair, group 2 standard, single power option, sling/solid seat/back, patient weight capacity up to and including 300 pounds.
K0836	Power wheelchair, group 2 standard, single power option, captains chair, patient weight capacity up to and including 300 pounds.
K0837	Power wheelchair, group 2 heavy duty, single power option, sling/solid seat/back, patient weight capacity 301 to 450 pounds.
K0838	Power wheelchair, group 2 heavy duty, single power option, captains chair, patient weight capacity 301 to 450 pounds.
K0839	Power wheelchair, group 2 very heavy duty, single power option, sling/solid seat/back, patient weight capacity 451 to 600 pounds.
K0840	Power wheelchair, group 2 extra heavy duty, single power option, sling/solid seat/back, patient weight capacity 601 pounds or more.
K0841	Power wheelchair, group 2 standard, multiple power option, sling/solid seat/back, patient weight capacity up to and including 300 pounds.
K0842	Power wheelchair, group 2 standard, multiple power option, captains chair, patient weight capacity up to and including 300 pounds.
K0843	Power wheelchair, group 2 heavy duty, multiple power option, sling/solid seat/back, patient weight capacity 301 to 450 pounds.
K0848	Power wheelchair, group 3 standard, sling/solid seat/back, patient weight capacity up to and including 300 pounds.
K0849	Power wheelchair, group 3 standard, captains chair, patient weight capacity up to and including 300 pounds.
K0850	Power wheelchair, group 3 heavy duty, sling/solid seat/back, patient weight capacity 301 to 450 pounds.
K0851	Power wheelchair, group 3 heavy duty, captains chair, patient weight capacity 301 to 450 pounds.
K0852	Power wheelchair, group 3 very heavy duty, sling/solid seat/back, patient weight capacity 451 to 600 pounds.
K0853	Power wheelchair, group 3 very heavy duty, captains chair, patient weight capacity 451 to 600 pounds.
K0854	Power wheelchair, group 3 extra heavy duty, sling/solid seat/back, patient weight capacity 601 pounds or more.
K0855	Power wheelchair, group 3 extra heavy duty, captains chair, patient weight capacity 601 pounds or more.

These codes will be subject to the requirements of the prior authorization program for certain DMEPOS items as outlined in § 414.234. We believe continued prior authorization of these codes will help further our program integrity goals of reducing fraud, waste, and abuse, while protecting access to care. We will implement a prior authorization program for these codes nationwide, for dates of service beginning September 1, 2018. This approach will allow continuity for those suppliers in the 19 states familiar with prior authorization of PMDs under the demonstration, and allows sufficient time for education and outreach to suppliers in the remaining states.

HCPCS codes K0856 and K0861, which we placed on the Required Prior Authorization List in a December 21, 2016 notice (81 FR 93636), will continue to be subject to the requirements of prior authorization as well.

Although the PMD demonstration's prior authorization process is similar to the process used for those items on the Required Prior Authorization List, some differences do exist. In particular, items on the Required Prior Authorization List require prior authorization as a condition of payment. As such, lack of a provisionally affirmed prior authorization request will result in a claim denial. Under the PMD demonstration, requesting prior authorization is optional, and claims submitted for payment without an associated prior authorization decision are subject to prepayment review and assessed a 25-percent reduction in Medicare payment if found payable. Additionally, under the PMD demonstration, physicians/treating practitioners may submit prior authorization requests and are eligible to bill HCPCS code G9156 for an incentive payment. This process is not available for items on the Required Prior Authorization List.

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 items subject to prior authorization, for communicating a provisionally affirmed or non-affirmed decision to the requester. In the December 30, 2015 final rule, to allow us to safeguard beneficiary access to care, we stated that this approach to final timelines provides the flexibility to develop a process that involves fewer days, as may be appropriate. If at any time we become aware that the prior authorization process is creating barriers to care, we can suspend the program.

The updated Required Prior Authorization list is 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.* We will post additional educational resources to the website.

III. Collection of Information Requirements

This notice announces the addition of DMEPOS items on the Required Prior Authorization List and does not impose any new information collection burden under the Paperwork Reduction Act of 1995. However, there is an information collection burden associated with this program that is currently approved under OMB control number 0938–1293 which expires February 28, 2019.

Dated: May 14, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2018–11953 Filed 6–1–18; 4:15 pm]

BILLING CODE 4120–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 13–249; FCC 18–64]

Revitalization of the AM Radio Service

AGENCY: Federal Communications Commission.

ACTION: Denial of petition for reconsideration; dismissal of petition for emergency partial stay and processing freeze pending review of petition for reconsideration and motion for extension of time.

SUMMARY: This document denies the Petition for Reconsideration of the Second Report and Order in this proceeding, filed by Prometheus Radio Project (Prometheus) on April 10, 2017. This document dismisses as moot the Petition for Emergency Partial Stay and Processing Freeze Pending Review of Petition for Reconsideration filed by Prometheus April 3, 2017, and the Motion for Extension of Time filed by Prometheus May 11, 2017.

DATES: June 5, 2018.

ADDRESSES: Federal Communications Commission, 445 12th Street SW, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Albert Shuldiner, Chief, Media Bureau, Audio Division, (202) 418–2700 or *Albert.Shuldiner@fcc.gov;* Thomas Nessinger, Senior Counsel, Media Bureau, Audio Division, (202) 418–2700 or *Thomas.Nessinger@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Order on Reconsideration, MB Docket No. 13–249, FCC 18–64, adopted on May 21, 2018, and released on May 22, 2018. The full text of this document is available for public inspection and copying during regular business hours in the FCC Reference Center, Federal Communications Commission, 445 12th Street SW, Washington, DC 20554. This document will also be available via ECFS at *https://www.fcc.gov/ecfs/.* Documents will be available electronically in ASCII, Microsoft Word, and/or Adobe Acrobat. Copies of the materials can be obtained from the FCC's Reference Information Center at (202) 418–0270. Alternative formats are available for people with disabilities (Braille, large print, electronic files, audio format), by sending an email to *fcc504@fcc.gov* or calling the Commission's Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY). This document is not subject to the Congressional Review Act. The Commission is, therefore, not required to submit a copy of this Order on Reconsideration to the General Accounting Office pursuant to the Congressional Review Act, see 5 U.S.C. 801(a)(1)(A), because the Petition for Reconsideration was denied and the Petition for Emergency Stay and Motion for Extension of Time were dismissed as moot.

The Commission rejected Prometheus's contentions that the Commission's decision not to adopt a proposed distance limit for siting cross-service FM translator stations (translators re-broadcasting AM station signals) was not a logical outgrowth of the proposed rule and was arbitrary and capricious. It found that the decision not to adopt the proposed 40-mile limit was reasonably foreseeable, especially given that commenters had proposed omitting the 40-mile limit and that Prometheus had access to those comments. The Commission further found that its actions were not arbitrary and capricious, finding that Prometheus's contentions do not raise legitimate concerns and are at best speculative. Prometheus did not provide evidence that omission of a distance limit encourages translators to ''box in'' incumbent low-power FM (LPFM) stations, restricting their ability to change sites. Additionally, the