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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-484; CMS-846-849, 854, 10125 and 10126; CMS-10379; and CMS-10418]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the Federal Register concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**:

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. Electronically. You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. By regular mail. You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attention: Document Identifier/OMB Control Number _____

Room C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.
2. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.
3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786-1326.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see ADDRESSES).

CMS-484 Attending Physician's Certification of Medical Necessity for Home Oxygen Therapy and Supporting Regulations

CMS-846-849, 854, 10125 and 10126 Durable Medical Equipment Medicare Administrative Contractors (MAC) Regional Carrier, Certificate of Medical Necessity and Supporting Documentation

CMS-10379 Rate Increase Disclosure and Review Reporting Requirements

CMS-10418 Medical Loss Ratio Annual Reports, MLR Notices, and Recordkeeping Requirements

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

1. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Attending Physician's Certification of Medical Necessity for Home Oxygen Therapy and Supporting Regulations; Use: Under Section 1862(a)(1)(A) of the Social Security Act (the Act), 42 U.S.C. §1395y(a), the Secretary may only pay for items and services that

are “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” In order to assure this, CMS and its contractors develop Medical policies that specify the circumstances under which an item or service can be covered. The certificate of medical necessity (CMN) provides a mechanism for suppliers of Durable Medical Equipment, defined in 42 U.S.C. §1395x (n), and Medical Equipment and Supplies defined in 42 U.S.C. §1395j(5), to demonstrate that the item being provided meets the criteria for Medicare coverage. Section 1833(e), 42 U.S.C. §1395l(e), provides that no payment can be made to any provider of services, or other person, unless that person has furnished the information necessary for Medicare or its contractor to determine the amounts due to be paid. Certain individuals can use a CMN to furnish this information, rather than having to produce large quantities of medical records for every claim they submit for payment. Under Section 1834(j)(2) of the Act, 42 U.S.C. §1395m(j)(2), suppliers of DME items are prohibited from providing medical information to physicians when a CMN is being completed to document medical necessity. The physician who orders the item is responsible for providing the information necessary to demonstrate that the item provided is reasonable and necessary and the supplier shall also list on the CMN the fee schedule amount and the suppliers charge for the medical equipment or supplies being furnished prior to distribution of such certificate to the physician. Any supplier of medical equipment who knowingly and willfully distributes a CMN in violation of this restriction is subject to penalties, including civil money penalties (42 U.S.C. §1395m (j)(2)(A)(iii)). Under Section 42 Code of Federal Regulations §410.38 and §424.5, Medicare has the legal authority to collect sufficient information to determine payment for oxygen, and oxygen equipment. Oxygen and oxygen equipment is by far the largest single total charge of all items paid under durable medical equipment coverage authority. Detailed criteria concerning coverage of home oxygen therapy are found in Medicare Carriers Manual

Chapter II-Coverage Issues Appendix, Section 60-4. For Medicare to consider any item for coverage and payment, the information submitted by the supplier (e.g., claims and CMNs), including documentation in the patient's medical records must corroborate that the patient meets Medicare coverage criteria. The patient's medical records may include: physician's office records; hospital records; nursing home records; home health agency records; records from other healthcare professionals or test reports. This documentation must be available to the DME MACs upon request. Form Number: CMS-484 (OMB Control Number: 0938-0534); Frequency: Occasionally; Affected Public: Private Sector: Business or other for-profits, Not-for-profits; Number of Respondents: 8,880; Total Annual Responses: 1,632,000; Total Annual Hours: 326,500. (For policy questions regarding this collection contact Paula Smith at 410-786-4709.)

2. Type of Information Collection Request: Revision of a currently approved collection; Title of Information Collection: Durable Medical Equipment Medicare Administrative Contractors (MAC) Regional Carrier, Certificate of Medical Necessity and Supporting Documentation; Use: The certificates of medical necessity (CMNs) collect information required to help determine the medical necessity of certain items. CMS requires CMNs where there may be a vulnerability to the Medicare program. Each initial claim for these items must have an associated CMN for the beneficiary. Suppliers (those who bill for the items) complete the administrative information (e.g., patient's name and address, items ordered, etc.) on each CMN. The 1994 Amendments to the Social Security Act require that the supplier also provide a narrative description of the items ordered and all related accessories, their charge for each of these items, and the Medicare fee schedule allowance (where applicable). The supplier then sends the CMN to the treating physician or other clinicians (e.g., physician assistant, LPN, etc.) who completes questions pertaining to the beneficiary's medical condition and signs the CMN. The physician or other clinician returns the CMN to the supplier who

has the option to maintain a copy and then submits the CMN (paper or electronic) to CMS, along with a claim for reimbursement. This clearance request is for CMNs with the form numbers, CMS CMS-846-849, 854, 10125 and 10126. Form Number: CMS-846-849, 854, 10125 and 10126 (OMB Control Number: 0938-0679); Frequency: Occasionally; Affected Public: Individuals or Households; Number of Respondents: 462,000; Total Annual Responses: 462,000; Total Annual Hours: 418,563. (For policy questions regarding this collection contact Paula Smith at 410-786-4709.)

3. Type of Information Collection Request: Revision of a currently approved collection; Title of Information Collection: Rate Increase Disclosure and Review Reporting Requirements; Use: Section 1003 of the Affordable Care Act adds a new section 2794 of the PHS Act which directs the Secretary of the Department of Health and Human Services (the Secretary), in conjunction with the states, to establish a process for the annual review of “unreasonable increases in premiums for health insurance coverage.” The statute provides that health insurance issuers must submit to the Secretary and the applicable state justifications for unreasonable premium increases prior to the implementation of the increases. Section 2794 also specifies that beginning with plan years beginning in 2014, the Secretary, in conjunction with the states, shall monitor premium increases of health insurance coverage offered through an Exchange and outside of an Exchange.

Section 2794 directs the Secretary to ensure the public disclosure of information and justification relating to unreasonable rate increases. Section 2794 requires that health insurance issuers submit justification for an unreasonable rate increase to CMS and the relevant state prior to its implementation. Additionally, section 2794 requires that rate increases effective in 2014 (submitted for review in 2013) be monitored by the Secretary, in conjunction with the states. To those ends, Section 154 of the CFR establishes various reporting requirements for health

insurance issuers, including a Preliminary Justification for a proposed rate increase, a Final Justification for any rate increase determined by a state or CMS to be unreasonable, and a notification requirement for unreasonable rate increases which the issuer will not implement.

In order to obtain the information necessary to monitor premium increases of health insurance coverage offered through an Exchange and outside of an Exchange, 45 CFR 154.215 would require health insurance issuers to submit the Unified Rate Review Template for all single risk pool coverage products in the individual or small group (or merged) market, regardless of whether any plan within a product is subject to a rate increase. That regulation would also require health insurance issuers to submit an Actuarial Memorandum (in addition to the Unified Rate Review Template) when a plan within a product is subject to a rate increase. Although the two required documents are submitted at the risk pool level, the requirement to submit is based on increases at the plan level.

In order to conduct a review to assess reasonableness when a plan within a product has a rate increase that is subject to review, health insurance issuers would be required to submit a written description justifying the increase (in addition to the Unified Rate Review Template and Actuarial Memorandum) . Although the required documents are submitted at the risk pool level, the requirement to submit is based on increases at the plan level. Form Number: CMS–10379 (OMB Control Number: 0938–1141); Frequency: Yearly; Affected Public: State and Private sector (Business or other for-profits and Not-for-profit institutions); Number of Respondents: 1,081; Total Annual Responses: 1,621; Total Annual Hours: 17,837. (For policy questions regarding this collection contact Lisa Cuzzo at 410-786-1746.)

4. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Medical Loss Ratio Annual Reports, MLR Notices, and Recordkeeping

Requirements; Use: Under Section 2718 of the Affordable Care Act and implementing regulation at 45 CFR Part 158, a health insurance issuer (issuer) offering group or individual health insurance coverage must submit a report to the Secretary concerning the amount the issuer spends each year on claims, quality improvement expenses, non-claims costs, Federal and State taxes and licensing and regulatory fees, the amount of earned premium, and beginning with the 2014 reporting year, the amounts related to the transitional reinsurance, risk adjustment, and risk corridors. An issuer must provide an annual rebate if the amount it spends on certain costs compared to its premium revenue (excluding Federal and States taxes and licensing and regulatory fees) does not meet a certain ratio, referred to as the medical loss ratio (MLR). Each issuer is required to submit annually MLR data, including information about any rebates it must provide, on a form prescribed by CMS, for each State in which the issuer conducts business. Each issuer is also required to provide a rebate notice to each policyholder that is owed a rebate and each subscriber of policyholders that are owed a rebate for any given MLR reporting year. Additionally, each issuer is required to maintain for a period of seven years all documents, records and other evidence that support the data included in each issuer's annual report to the Secretary. Under Section 1342 of the Patient Protection and Affordable Care Act and implementing regulation at 45 CFR Part 153, issuers of qualified health plans (QHPs) must participate in a risk corridors program. A QHP issuer is required to pay charges to or receive payments from CMS based on the ratio of the issuer's allowable costs to the target amount. Each QHP issuer is required to submit an annual report to CMS concerning the issuer's allowable costs, allowable administrative costs, and the amount of premium.

The 2015 MLR Reporting Form and Instructions reflect changes for the 2015 reporting / benefit year and beyond. In 2016, it is expected that issuers will submit fewer reports and send fewer notices to policyholders and subscribers, which will reduce burden on issuers. On the other

hand, it is expected that issuers will send more rebate checks in the mail to individual market policyholders, which will increase burden for some issuers. It is estimated that there will be a net reduction in total burden from 271,600 to 235,148. Form Number: CMS-10418 (OMB Control Number: 0938-1164); Frequency: Annually; Affected Public: Private Sector, Business or other for-profits and not-for-profit institutions; Number of Respondents: 538; Number of Responses: 2,818; Total Annual Hours: 235,148. (For policy questions regarding this collection contact Christina Whitefield at 301-492-4172.)

Dated: February 16, 2016.

William N. Parham, III,

Director, Paperwork Reduction Staff,

Office of Strategic Operations and Regulatory Affairs.

Billing Code: 4120-01-U-P

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