DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–6063–N]

Medicare Program; Prior Authorization of Repetitive Scheduled Nonemergent Ambulance Transports

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

ACTION: Notice.

SUMMARY: This notice announces a 3-year Medicare Prior Authorization model for repetitive scheduled nonemergent ambulance transport in the states of New Jersey, Pennsylvania, and South Carolina where there have been high incidences of improper payments for these services.

DATES: This model will begin on December 1, 2014 in South Carolina, New Jersey, and Pennsylvania.

FOR FURTHER INFORMATION CONTACT: Angela Gaston, (410) 786–7409. Questions regarding the Medicare Prior Authorization Model for Repetitive Scheduled Nonemergent Ambulance Transport should be sent to *AmbulancePA@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Medicare covers ambulance services, including air ambulance (fixed wing and rotary wing) services, when furnished to a beneficiary whose medical condition is such that other means of transportation are contraindicated. The beneficiary's condition must require both the ambulance transportation itself and the level of service provided in order for the billed service to be considered medically necessary.

Nonemergent transportation by ambulance is appropriate if either—(1) the beneficiary is bed-confined and it is documented that the beneficiary's condition is such that other methods of transportation are contraindicated; or (2) the beneficiary's medical condition, regardless of bed confinement, is such that transportation by ambulance is medically required. Thus, bed confinement is not the sole criterion in determining the medical necessity of nonemergent ambulance transportation; rather, it is one factor that is considered in medical necessity determinations.[1]

A repetitive ambulance service is defined as medically necessary ambulance transportation that is furnished in 3 round trips or more times during a 10-day period, or at least once per week for at least 3 weeks.[2] Repetitive ambulance services are often needed by beneficiaries receiving dialysis, wound care, or cancer treatment.

Medicare may cover repetitive, scheduled, nonemergent transportation by ambulance if—(1) the medical necessity requirements described previously are met; and (2) the ambulance provider/supplier, before furnishing the service to the beneficiary, obtains a written order from the beneficiary's attending physician certifying that the medical necessity requirements are met (see 42 CFR 410.40(d)(1) and (2)).[3]

In addition to the medical necessity requirements, the service must meet all other Medicare coverage and payment requirements, including requirements relating to the origin and destination of the transportation, vehicle and staff, and billing and reporting. Additional information about Medicare coverage of ambulance services can be found in 42 CFR 410.40, 410.41, and in the Medicare Benefit Policy Manual, Chapter 10, at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c10.pdf.*

According to a study published by the Government Accountability Office in October 2012, entitled ''Costs and Medicare Margins Varied Widely; Transports of Beneficiaries Have Increased'', the number of Basic Life Support (BLS) nonemergent transports for Medicare fee-for-service beneficiaries increased by 59 percent from 2004 to 2010. A similar finding published by the Department of Health and Human Services Office of Inspector General in a 2006 study, entitled ''Medicare Payments for Ambulance Transports'', indicated a 20 percent nationwide improper payment rate for nonemergent ambulance transport. Likewise, in June 2013, the Medicare Payment Advisory Commission published a report[4] that included an analysis of nonemergent ambulance transports to dialysis facilities and found that, during the 5-year period between 2007 and 2011, the volume of transports to and from a dialysis facility increased 20 percent, more than twice the rate of all other ambulance transports combined.

Section 1115A of the Act authorizes the Secretary to test innovative payment and service delivery models to reduce program expenditures, while preserving or enhancing the quality of care furnished to Medicare, Medicaid and Children's Health Insurance Program beneficiaries.

Section 1115A(d)(1) of the Act authorizes the Secretary to waive such requirements of Titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), and 1903(m)(2)(A)(iii) of the Act as may be necessary solely for purposes of carrying out section 1115A of the Act with respect to testing models described in section 1115A(b) of the Act. For these models, consistent with this standard, we will waive such provisions of sections 1834(a)(15) and 1869(h) of the Act that limit our ability to conduct prior authorization. While these provisions are specific to durable medical equipment and physician services, we will waive any portion of these sections as well as any portion of 42 CFR 410.20(d), which implements section 1869(h) of the Act, that could be construed to limit our ability to conduct prior authorization. We have determined that the implementation of this model does not require the waiver of any fraud and abuse law, including sections 1128A, 1128B, and 1877 of the Act. Thus, providers and suppliers affected by this model must comply with all applicable fraud and abuse laws.

II. Provisions of the Notice

We plan to implement a 3-year Medicare Prior Authorization process for repetitive scheduled nonemergent ambulance transport rendered by ambulance providers/suppliers garaged in 3 states (New Jersey, Pennsylvania, and South Carolina). These states were selected as the initial states for the model because of their high utilization and improper payment rates for these services. The model will begin in on December 1, 2014, in South Carolina, New Jersey, and Pennsylvania.

We plan to test whether prior authorization helps reduce expenditures, while maintaining or improving quality of care, using a model that would establish a prior authorization process for repetitive scheduled nonemergent ambulance transport to reduce utilization of services that do not comply with Medicare policy.

We plan to use this prior authorization process to ensure that all relevant clinical or medical documentation requirements are met before services are rendered to beneficiaries and before claims are

[1] 42 CFR 410.40(d)(1).

[2] Program Memorandum Intermediaries/Carriers, Transmittal AB–03–106.

[3] Per 42 CFR 410.40(d)(2), the physician's order must be dated no earlier than 60 days before the date the service is furnished.

[4] Medicare Payment Advisory Commission, June 2013, pages 167–193.

submitted for payment. This prior authorization process will further ensure that payment complies with Medicare documentation, coverage, payment, and coding rules.

The use of prior authorization will not create new clinical documentation requirements. Instead, it will require the same information that is already required to support Medicare payment, just earlier in the process. Prior authorization allows providers and suppliers to address issues with claims prior to rendering services.

The prior authorization process under this model will be available for the following codes for Medicare payment:

- A0425 Ambulance service, basic life support (BLS)/advanced life support (ALS) ground mileage (per statute mile).
- A0426 Ambulance service, advanced life support, nonemergency transport, Level 1 (ALS1).
- A0428 Ambulance service, basic life support (BLS), nonemergency transport.

Prior to the start of the model, we will conduct (and thereafter will continue to conduct) outreach and education to ambulance providers/suppliers, as well as beneficiaries, through such methods as open door forums, frequently asked questions (FAQs) on our Web site, other Web site postings, and educational materials issued by the Medicare Administrative Contractors (MACs). Additional information about the implementation of the prior authorization model is available on the CMS Web site at *http://go.cms.gov/PAAmbulance.*

Under this model, an ambulance provider/supplier or beneficiary will be encouraged to submit to the MAC a request for prior authorization along with all relevant documentation to support Medicare coverage of a repetitive scheduled nonemergent ambulance transport. Submitting a prior authorization request will be voluntary. (However, if prior authorization has not been requested before the fourth round trip in a 30-day period, the claims will be stopped for pre-payment review).

In order to be provisionally affirmed, the request for prior authorization must meet all applicable rules and policies, and any local coverage determination (LCD) requirements for ambulance transport claims. A provisional affirmation is a preliminary finding that a future claim submitted to Medicare for the service likely meets Medicare's coverage, coding, and payment requirements. After receipt of all relevant documentation, the MACs will make every effort to conduct a review and postmark the notification of their decision on a prior authorization request within 10 business days for an initial submission. Notification will be provided to the ambulance provider/supplier and to the beneficiary. If a subsequent prior authorization request is submitted after a nonaffirmative decision on an initial prior authorization request, the MACs will make every effort to conduct a review and postmark the notification of their decision on the request within 20 business days.

An ambulance provider/supplier or beneficiary may request an expedited review when the standard timeframe for making a prior authorization decision could jeopardize the life or health of the beneficiary. If the MAC agrees that the standard review timeframe would put the beneficiary at risk, the MAC will make reasonable efforts to communicate a decision within 2 business days of receipt of all applicable Medicare-required documentation. As this model is for nonemergent services only, we expect requests for expedited reviews to be extremely rare.

A provisional affirmative prior authorization decision may affirm a specified number of trips within a specific amount of time. The prior authorization decision, justified by the beneficiary's condition, may affirm up to 40 round trips (which equates to 80 one-way trips) per prior authorization request in a 60-day period. Alternatively, a provisional affirmative prior authorization decision may affirm less than 40 round trips in a 60-day period, or may affirm a request that seeks to provide a specified number of transports (40 round trips or less) in less than a 60-day period. A provisional affirmative decision can be for all or part of the requested number of trips. Transports exceeding 40 round trips (or 80 one-way trips) in a 60-day period will require an additional prior authorization request.

The following describes examples of various prior authorization scenarios:

- *Scenario 1:* When an ambulance provider/supplier or beneficiary submits a prior authorization request to the MAC with appropriate documentation and all relevant Medicare coverage and documentation requirements are met for the ambulance transport, the MAC will send a provisional affirmative prior authorization decision to the ambulance provider/supplier and to the beneficiary. When the claim is submitted to the MAC by the ambulance provider/supplier, it is linked to the prior authorization via the claims processing system and the claim will be paid so long as all Medicare coding, billing, and coverage requirements are met. However, after submission, the claim could be denied for technical reasons, such as the claim was a duplicate claim or the claim was for a deceased beneficiary. In addition, a claim denial could occur since certain documentation, such as the trip record, needed in support of the claim cannot be reviewed on a prior authorization request.
- *Scenario 2:* When an ambulance provider/supplier or beneficiary submits a prior authorization request, but all relevant Medicare coverage requirements are not met, the MAC will send a nonaffirmative prior authorization decision to the ambulance provider/supplier and to the beneficiary, advising them that Medicare will not pay for the service. The provider/supplier or beneficiary may then resubmit the request with documentation showing that Medicare requirements have been met. Alternatively, an ambulance provider/supplier could render the service, and submit a claim with a nonaffirmative prior authorization tracking number, at which point the MAC would deny the claim. The ambulance provider/supplier and/or the beneficiary would then have the Medicare denial for secondary insurance purposes and would have the opportunity to submit an appeal of the claim denial if they believe Medicare coverage was denied inappropriately.
- *Scenario 3:* When an ambulance provider/supplier or beneficiary submits a prior authorization request with incomplete documentation, a detailed decision letter will be sent to the ambulance provider/supplier and to the beneficiary, with an explanation of what information is missing. The ambulance provider/supplier or beneficiary can rectify the situation and resubmit the prior authorization request with appropriate documentation.
- *Scenario 4:* When an ambulance provider or supplier renders a service to a beneficiary that is subject to the prior authorization process, and the claim is submitted to the MAC for payment without requesting a prior authorization, the claim will be stopped for prepayment review and documentation will be requested.

++ If the claim is determined to be not medically necessary or to be insufficiently documented, the claim will be denied, and all current policies and procedures regarding liability for payment will apply. The ambulance provider/supplier or the beneficiary or both can appeal the claim denial if they believe the denial was inappropriate.

++ If the claim is determined to be payable, it will be paid.

Under the model, we will work to limit any adverse impact on

beneficiaries and to educate beneficiaries about the process. If a prior authorization request is not affirmed, and the claim is still submitted by the provider/supplier, the claim will be denied in full, but beneficiaries will continue to have all applicable administrative appeal rights.

Only one prior authorization request per beneficiary per designated time period can be provisionally affirmed. If the initial provider/supplier cannot complete the total number of prior authorized transports (for example, the initial ambulance company closes or no longer services that area), the initial request is cancelled. In this situation, a subsequent prior authorization request may be submitted for the same beneficiary and must include the required documentation in the submission. If multiple ambulance providers/suppliers are providing transports to the beneficiary during the same or overlapping time period, the prior authorization decision will only cover the provider/supplier indicated in the provisionally affirmed prior authorization request. Any provider/supplier submitting claims for repetitive scheduled nonemergent ambulance transports for which no prior authorization request is recorded will be subject to 100 percent prepayment medical review of those claims.

Additional information is available on the CMS Web site at *http://go.cms.gov/PAAmbulance.*

III. Collection of Information Requirements

Section 1115A(d)(3) of the Act, as added by section 3021 of the Affordable Care Act, states that chapter 35 of title 44, United States Code (the Paperwork Reduction Act of 1995), shall not apply to the testing and evaluation of models or expansion of such models under this section. Consequently, this document need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

Authority: Section 1115A of the Social Security Act.

Dated: October 8, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0279]

Agency Information Collection Activities; Proposed Collection; Comment Request; Prescription Drug Marketing Act of 1987; Administrative Procedures, Policies, and Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. 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 of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection in the regulations on the Prescription Drug Marketing Act of 1987; Administrative Procedures, Policies, and Requirements.

DATES: Submit either electronic or written comments on the collection of information by January 13, 2015.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA 305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: 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. ''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 (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Prescription Drug Marketing Act of 1987; Administrative Procedures, Policies, and Requirements—21 CFR Part 203—(OMB Control Number 0910–0435)—Extension

FDA is requesting OMB approval under the PRA (44 U.S.C. 3501–3520) for the reporting and recordkeeping requirements contained in the regulations implementing the Prescription Drug Marketing Act of 1987 (PDMA). PDMA was intended to ensure that drug products purchased by consumers are safe and effective and to avoid an unacceptable risk that counterfeit, adulterated, misbranded, subpotent, or expired drugs are sold.

PDMA was enacted by Congress because there were insufficient safeguards in the drug distribution system to prevent the introduction and retail sale of substandard, ineffective, or counterfeit drugs, and that a wholesale drug diversion submarket had developed that prevented effective control over the true sources of drugs.

Congress found that large amounts of drugs had been reimported into the United States as U.S. goods returned causing a health and safety risk to U.S. consumers because the drugs may become subpotent or adulterated during foreign handling and shipping. Congress also found that a ready market for prescription drug reimports had been the catalyst for a continuing series of