contract, or the issuance or retention of a license, grant, or other benefit, to the extent that the information is relevant and necessary to the requesting agency's decision.

h. To the Office of Management and Budget (OMB) when necessary to the review of private relief legislation pursuant to OMB Circular No. A–19.

i. To a Federal, State, or local agency, or other appropriate entities or individuals, or through established liaison channels to selected foreign governments, in order to enable an intelligence agency to carry out its responsibilities under the National Security Act of 1947, as amended; the CIA Act of 1949, as amended; Executive Order 12333 or any successor order; and applicable national security directives, or classified implementing procedures approved by the Attorney General and promulgated pursuant to such statutes, orders, or Directives.

j. To designated agency personnel for controlled access to specific records for the purposes of performing authorized audit or authorized oversight and administrative functions. All access is controlled systematically through authentication using PIV credentials based on access and authorization rules for specific audit and administrative functions.

k. To the Office of Personnel Management (OPM), the Office of Management and Budget (OMB), the Government Accountability Office (GAO), or other Federal agency in accordance with the agency's responsibility for evaluation of Federal personnel management.

l. To the Federal Bureau of Investigation for the FBI National Criminal History check.

m. To appropriate agencies, entities, and persons when (1) the Agency suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised; (2) the Agency has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by GSA or another agency or entity) that rely upon the compromised information; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with GSA's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored in electronic media and in paper files.

RETRIEVABILITY:

Records may be retrieved by name of the individual, Cardholder Unique Identification Number, Applicant ID, Social Security Number, and/or by any other unique individual identifier.

SAFEGUARDS:

Consistent with the requirements of the Federal Information Security Management Act (Pub. L. 107–296), and associated OMB policies, standards and guidance from the National Institute of Standards and Technology, and the General Services Administration, the GSA HSPD–12 managed service office protects all records from unauthorized access through appropriate administrative, physical, and technical safeguards. Access is restricted on a ''need to know'' basis, utilization of PIV Card access, secure VPN for Web access, and locks on doors and approved storage containers. Buildings have security guards and secured doors. All entrances are monitored through electronic surveillance equipment. The hosting facility is supported by 24/7 onsite hosting and network monitoring by trained technical staff. Physical security controls include: Indoor and outdoor security monitoring and surveillance; badge and picture ID access screening; biometric access screening. Personally identifiable information is safeguarded and protected in conformance with all Federal statutory and OMB guidance requirements. All access has role-based restrictions, and individuals with access privileges have undergone vetting and suitability screening. All data is encrypted in transit. While it is not contemplated, any system records stored on mobile computers or mobile devices will be encrypted. GSA maintains an audit trail and performs random periodic reviews to identify unauthorized access. Persons given roles in the PIV process must be approved by the Government and complete training specific to their roles to ensure they are knowledgeable about how to protect personally identifiable information.

RETENTION AND DISPOSAL:

Disposition of records will be according to NARA disposition authority N1–269–06–1 (pending).

SYSTEM MANAGER AND ADDRESS:

Director, HSPD–12 Managed Service Office, Federal Acquisition Service (FAS), General Services Administration, 1800 F Street NW., 4th Floor, Washington, DC 20405.

NOTIFICATION PROCEDURE:

A request for access to records in this system may be made by writing to the System Manager. When requesting notification of or access to records covered by this Notice, an individual should provide his/her full name, date of birth, agency name, and work location. An individual requesting notification of records must provide identity documents sufficient to satisfy the custodian of the records that the requester is entitled to access, such as a government-issued photo ID.

RECORD ACCESS PROCEDURES:

Same as Notification Procedure above.

CONTESTING RECORD PROCEDURES:

Same as Notification Procedure above. State clearly and concisely the information being contested, the reasons for contesting it, and the proposed amendment to the information sought.

RECORD SOURCE CATEGORIES:

Employee, contractor, or applicant; sponsoring agency; former sponsoring agency; other Federal agencies; contract employer; former employer.

[FR Doc. 2015–26940 Filed 10–22–15; 8:45 am]

BILLING CODE 6820–38–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–6063–N2]

Medicare Program; Expansion of Prior Authorization for Repetitive Scheduled Non-Emergent Ambulance Transports

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

ACTION: Notice.

SUMMARY: This notice announces an expansion of the 3-year Medicare Prior Authorization Model for Repetitive Scheduled Non-Emergent Ambulance Transport in accordance with section 515(a) of the Medicare Access and CHIP Reauthorization Act of 2015. The model is being expanded to the states of Maryland, Delaware, the District of Columbia, North Carolina, West Virginia, and Virginia.

DATES: This expansion will begin on January 1, 2016 in Maryland, Delaware,

the District of Columbia, North Carolina, Virginia, and West Virginia.

FOR FURTHER INFORMATION CONTACT: Angela Gaston, (410) 786–7409.

Questions regarding the Medicare Prior Authorization Model Expansion for Repetitive Scheduled Non-Emergent Ambulance Transport should be sent to *AmbulancePA@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Medicare may cover ambulance services, including air ambulance (fixed-wing and rotary-wing) services, if the ambulance service is 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.

Non-emergent transportation by ambulance is appropriate if either the—(1) beneficiary is bed-confined and it is documented that the beneficiary's condition is such that other methods of transportation are contraindicated; or (2) 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 non-emergent 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 or more round trips during a 10-day period, or at least 1 round trip per week for at least 3 weeks.[2] Repetitive ambulance services are often needed by beneficiaries receiving dialysis or cancer treatment.

Medicare may cover repetitive, scheduled, non-emergent transportation by ambulance if the—(1) medical necessity requirements described previously are met; and (2) 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 (Pub. 100–02), 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,'' [4] the number of basic life support (BLS) non-emergent 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,'' [5] indicated a 20-percent nationwide improper payment rate for non-emergent ambulance transport. Likewise, in June 2013, the Medicare Payment Advisory Commission published a report [6] that included an analysis of non-emergent 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 Social Security Act (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 physicians' 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

In the November 14, 2014 **Federal Register** (79 FR 68271), we published a notice entitled ''Medicare Program; Prior Authorization of Repetitive Scheduled Non-emergent Ambulance Transports,'' which announced the implementation of a 3-year Medicare Prior Authorization model that established a process for seeking prior authorizations for repetitive scheduled non-emergent 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 began on December 1, 2014, and will end in all 3 states on December 1, 2017. Prior authorization will not apply to or be given for services furnished after that date.

Section 515(a) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10), requires expansion of the previously referenced prior authorization model to cover, effective not later than January 1, 2016, states located in Medicare Administrative Contractor (MAC) regions L and 11 (consisting of Delaware, the District of Columbia, Maryland, New Jersey, Pennsylvania, North Carolina, South Carolina, West Virginia, and Virginia). As such, in accordance with section 515(a) of MACRA, our initial expansion of the prior authorization model for repetitive scheduled non-emergent ambulance transport will include six additional states: Delaware, the District of Columbia, Maryland, North Carolina, Virginia, and West Virginia. This expansion will begin on January 1, 2016. The model will end in all states on December 1, 2017. Prior authorization will not apply to or be given for services furnished after that date.

We will continue to test whether prior authorization helps reduce

[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] Government Accountability Office Cost and Medicare Margins Varied Widely; Transports of Beneficiaries Have Increased (October 2012).

[5] Office of Inspector General Medicare Payment for Ambulance Transport (January 2006).

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

expenditures, while maintaining or improving quality of care, using the established prior authorization process for repetitive scheduled non-emergent ambulance transport to reduce utilization of services that do not comply with Medicare policy.

We will continue to use this prior authorization process to help ensure that all relevant clinical or medical documentation requirements are met before services are furnished to beneficiaries and before claims are submitted for payment. This prior authorization process further helps to ensure that payment complies with Medicare documentation, coverage, payment, and coding rules.

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

The prior authorization process under this model will apply in the additional six states listed previously for the following codes for Medicare payment:

- A0426 Ambulance service, advanced life support, non-emergency transport, Level 1 (ALS1).
- A0428 Ambulance service, BLS, non-emergency transport.

While prior authorization in the additional six states is not needed for the mileage code, A0425, a prior authorization decision for an A0426 or A0428 code will automatically include the associated mileage code.

Prior to the start of the expansion, we will conduct (and thereafter will continue to conduct) outreach and education to ambulance providers/suppliers, as well as beneficiaries, through such methods as the issuance of an operational guide, frequently asked questions (FAQs) on our Web site, a beneficiary mailing, a physician letter explaining the ambulance providers/suppliers' need for the proper documentation, and educational events and materials issued by the 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 is encouraged to submit to the MAC a request for prior authorization along with all relevant documentation to support Medicare coverage of a repetitive scheduled non-emergent ambulance transport. Submitting a prior authorization request is voluntary. However, if prior authorization has not been requested by 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 non-affirmative 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 non-emergent 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 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 because 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 non-affirmative 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 furnish the service, and submit a claim with a non-affirmative prior authorization tracking number, at which point the MAC would deny the claim. The ambulance provider/supplier and 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 not to be 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 non-emergent ambulance transports for which no prior authorization request is recorded will be subject to 100 percent pre-payment 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.

IV. Regulatory Impact Statement

This document announces an expansion of the 3-year Medicare Prior Authorization Model for Repetitive Scheduled Non-Emergent Ambulance Transport. Therefore, there are no regulatory impact implications associated with this notice.

Authority: Section 1115A of the Social Security Act.

Dated: October 2, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2015–27030 Filed 10–22–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1960]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; MedWatch: The Food and Drug Administration Medical Products Reporting Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''MedWatch: The Food and Drug Administration Medical Products Reporting Program'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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: On June 11, 2015, the Agency submitted a proposed collection of information entitled ''MedWatch: The Food and Drug Administration Medical Products Reporting Program'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0291. The approval expires on September 30, 2018. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: October 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–26923 Filed 10–22–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1048]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Medical Device Labeling Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Medical Device Labeling Regulations'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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: On January 30, 2015, the Agency submitted a proposed collection of information entitled ''Medical Device Labeling Regulations'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0485. The approval expires on September 30, 2018. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: October 16, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–26986 Filed 10–22–15; 8:45 am]

BILLING CODE 4164–01–P