

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.*

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## 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, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@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.*

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## 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, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@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.*

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