

margin requirements for derivatives that reference SOFR and would help market participants compare SOFR to existing benchmarks. The Board recognizes that market participants might benefit from historical data. While longer histories of comparable commercially produced repo rates are publicly available, the Board believes that a significantly longer history of the Treasury repo rates may not be possible due to limitations on the availability of data. The Board and FRBNY will work with BNYM and DTCC to determine whether FRBNY can publish additional historical data for the Treasury repo rates.

Two commenters suggested that the proposed threshold of “greater than one basis point” for revising the proposed rates was too sensitive. Another commenter explained that its members had not achieved consensus on the threshold at which FRBNY should revise errors, but the commenter emphasized that FRBNY should articulate a clear rationale for its revision policy. The Board notes that, because FRBNY will round the Treasury repo rates to the nearest whole basis point, the threshold is effectively two basis points. The Board also notes that this is the same threshold employed for EFFR and OBFR, for which revisions are very rare. The Federal Reserve will periodically review the revision threshold to ensure that revisions are very rare and do not impose undue operational costs on users of the Treasury repo rates.

A commenter asked whether FRBNY would publish the proposed rates if relevant data sources were unavailable and, if so, whether FRBNY would correct such rates retroactively when data becomes available. Another commenter suggested that FRBNY should provide more information regarding the back-up repo market survey it would conduct if standard data sources are unavailable. As noted in the Request for Information, in the event that data sources are unavailable, the Treasury repo rates would be calculated based upon back-up repo market survey data collected from FRBNY’s primary dealer counterparties. FRBNY currently collects repo data from primary dealers each morning. Going forward, FRBNY will also collect data each afternoon. The afternoon survey will capture that day’s activity by primary dealers and will be available as a contingency data source for the following morning’s publication of the Treasury repo rates. The survey will request aggregated primary dealer activity in each of the market segments captured in the Treasury repo rates: Overnight tri-party Treasury repo transactions, overnight

Treasury repo transactions in the GCF market, and FICC-cleared bilateral Treasury repo transactions. For each of these market segments, each dealer will report its aggregate borrowing activity (excluding, to the extent possible, transactions between affiliated entities and transactions in which the Federal Reserve is a counterparty), along with the weighted-average rate of its borrowing. If FRBNY publishes Treasury repo rates that use survey data and subsequently receives updated data, FRBNY would issue same-day revisions at or around 2:30 p.m. ET if the use of updated data would result in the published rate changing by more than one basis point.

Finally, two commenters asked that FRBNY begin publishing the Treasury repo rates as soon as possible. FRBNY intends to begin publishing the Treasury repo rates in the second quarter of 2018.

4. Governance

A commenter suggested that governance arrangements for the Treasury repo rates should align with the *Principles for Financial Benchmarks* published by the International Organization of Securities Commissions (IOSCO) in July 2013.¹² FRBNY plans to publish an IOSCO statement of compliance covering the Treasury repo rates in the first half of 2018.

III. Conclusion

After considering public comments, the Board concludes that the public would benefit if FRBNY publishes the three Treasury repo rates as proposed, with certain modifications described above.

IV. Administrative Law

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3506; 5 CFR part 1320, Appendix A.1), the Board reviewed the Request for Information and this final notice under the authority delegated to the Board by the Office of Management and Budget. For purposes of calculating burden under the Paperwork Reduction Act, a “collection of information” involves 10 or more respondents. As noted above, the data to be used to produce the rates will be obtained solely from (1) BNYM with respect to tri-party GC repo data and (2) DTCC Solutions with respect to GCF repo data and DVP bilateral repo data. Therefore, producing the rates will not involve a collection of information pursuant to the Paperwork Reduction Act.

¹² See <https://www.iosco.org/library/pubdocs/pdf/IOSCOPD415.pdf>.

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) generally requires an agency to perform an initial and a final regulatory flexibility analysis on the impact a rule is expected to have on small entities. The RFA imposes these requirements in situations where an agency is required by law to publish a general notice of proposed rulemaking for any proposed rule. The production of the rates does not create any obligations or rights for any private parties, including any small entities, and so the Board was not required to publish a notice of proposed rulemaking. Accordingly, the RFA does not apply and an initial and final regulatory flexibility analysis is not required.

The Board did not receive any comments regarding the Paperwork Reduction Act or the RFA.

By order of the Board of Governors of the Federal Reserve System, December 7, 2017.

Ann E. Misback,

Secretary of the Board.

[FR Doc. 2017-26761 Filed 12-11-17; 8:45 am]

BILLING CODE 6210-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-6063-N3]

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

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

ACTION: Notice.

SUMMARY: This notice announces a 1-year extension of the Medicare Prior Authorization Model for Repetitive Scheduled Non-Emergent Ambulance Transport. The extension of this model is applicable to the following states and the District of Columbia: Delaware, Maryland, New Jersey, North Carolina, Pennsylvania, South Carolina, Virginia, and West Virginia.

DATES: This extension began on December 5, 2017 and ends on December 1, 2018. However, prior authorization is available upon provider, supplier, or beneficiary request for dates of service between December 2, 2017 and December 4, 2017.

FOR FURTHER INFORMATION CONTACT: Angela Gaston, (410) 786-7409. Questions regarding the Medicare Prior Authorization Model Extension 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. L. 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 report⁶ 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, as well as sections 1902(a)(1), 1902(a)(13), 1903(m)(2)(A)(iii), and 1934 (other than subsections (b)(1)(A) and (c)(5)) 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. Consistent with this standard, we will continue to waive the same provisions for the extension of this model as have been waived for the initial three years of the model. Additionally, 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.

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 requesting prior authorization 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 was originally scheduled to end in all 3 states on December 1, 2017.

In the October 23, 2015 **Federal Register** (80 FR 64418), we published a notice titled “Medicare Program; Expansion of Prior Authorization of Repetitive Scheduled Non-emergent Ambulance Transports,” which announced the inclusion of 6 additional states (Delaware, the District of Columbia, Maryland, North Carolina, West Virginia, and Virginia) in the Repetitive Scheduled Non-Emergent Ambulance Transport Prior Authorization model in accordance with section 515(a) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10). These 6 states began participation on January 1, 2016, and the model was originally scheduled to end in all nine model states on December 1, 2017.

II. Provisions of the Notice

This notice announces that the Medicare Prior Authorization Model for Repetitive Scheduled Non-Emergent Ambulance Transport is being extended in the current model states of Delaware, the District of Columbia, Maryland, New Jersey, North Carolina, Pennsylvania, South Carolina, Virginia, and West Virginia, effective December 5, 2017, for an additional year to allow for additional evaluation of the model. Repetitive, scheduled non-emergent ambulance transport claims with dates of service of December 2, 2017 through December 4, 2017 will not be stopped for prepayment review if prior authorization is not requested before the fourth round trip in a 30-day period; however, providers, suppliers, and beneficiaries may request prior authorization for these dates of service. The model will now end in all states on December 1, 2018. Prior authorization will not be available for repetitive

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.

scheduled non-emergent ambulance transportation services furnished after that date.

We will continue to test whether prior authorization helps reduce 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 continue to apply in the nine 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 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.

We have conducted and will continue to conduct outreach and education to ambulance providers/suppliers, as well as beneficiaries, through such methods as updating the operational guide, frequently asked questions (FAQs) on our website, a physician letter explaining the ambulance providers/suppliers' need for the proper documentation, and educational events and materials issued by the Medicare Administrative Contractors (MACs). We are also working to implement a new process that will help identify alternate transportation resources for beneficiaries who receive non-affirmative decisions. Additional information about the implementation of the prior authorization model is available on the CMS website at <http://go.cms.gov/PAAmbulance>.

Under this model, submitting a prior authorization request is voluntary.

However, 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. If prior authorization has not been requested by the fourth round trip in a 30-day period, the subsequent claims will be stopped for prepayment review.

In order for a prior authorization request to be provisionally affirmed, the request for prior authorization must meet all applicable rules and policies, including 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 resubmitted 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 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 the beneficiary. When the subsequent claim is submitted to the MAC by the ambulance provider/supplier, it is linked to the prior authorization decision via the claims processing system, and the claim will be paid so long as all Medicare coding, billing, and coverage requirements are met. However, 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 submitted with a prior authorization request because it is not available until after the service is provided.

- *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 additional 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 think 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 error(s) and resubmit the prior authorization request with appropriate documentation.

- **Scenario 4:** If an ambulance provider or supplier renders a service to a beneficiary and does not request prior authorization by the fourth round trip in a 30-day period, and the claim is submitted to the MAC for payment, then the claim will be stopped for prepayment review and documentation will be requested.

++ If the claim is determined to be for services that were not medically necessary or for which there was insufficient documentation, 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 non-affirmed, and the claim is still submitted by the ambulance provider/supplier, the claim will be denied, but beneficiaries will continue to have all applicable administrative appeal rights. We will also work to implement a process that will help identify alternate transportation resources for beneficiaries who receive non-affirmative decisions.

Only one prior authorization request per beneficiary per designated time period can be provisionally affirmed. If the initial ambulance 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 ambulance provider/supplier indicated in the provisionally affirmed prior authorization request. Any ambulance provider/supplier submitting claims for repetitive, scheduled non-emergent ambulance transports for which no prior authorization request is submitted by the fourth round trip in a 30-day period will be subject to 100

percent prepayment medical review of those claims.

Additional information is available on the CMS website at <http://go.cms.gov/PAAmbulance>.

III. Collection of Information Requirements

Section 1115A(d)(3) of the 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 a 1-year extension of the 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: November 16, 2017.

Seema Verma,
Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2017-26759 Filed 12-8-17; 4:15 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0523]

Agency Information Collection Activities: Submission for Office of Management and Budget Review; Comment Request; Applications for Food and Drug Administration Approval To Market a New Drug

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by January 11, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written

comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0001. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Application for FDA Approval To Market a New Drug

OMB Control Number 0910-0001—Extension

Under section 505(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(a)), a new drug may not be commercially marketed in the United States, imported, or exported from the United States, unless an approval of an application filed with FDA under section 505(b) or (j) of the FD&C Act is effective with respect to such drug. The Agency has codified regulations regarding applications for FDA approval to market a new drug under 21 CFR part 314. This collection of information supports the regulatory requirements found in those regulations. The collection of information is necessary for FDA to make a scientific and technical determination whether the product is safe and effective for use, and is summarized as follows:

Section 314.50(a) requires that an application form (Form FDA 356h) be submitted that includes information about the applicant, the submission, and a checklist of enclosures.

Section 314.50(b) requires that an index be submitted with the archival copy of the application and that it reference certain sections of the application.

Section 314.50(c) requires that a summary of the application be submitted that presents a good general synopsis of all the technical sections and other information in the application.

Section 314.50(d) requires that the new drug application (NDA) contain the following technical sections about the new drug: Chemistry, manufacturing,