Supporting Statement Part A
Proposed Repetitive, Scheduled Non-Emergent Ambulance Transport (RSNAT) Prior Authorization Process and Requirements for a Potential National Model
(CMS-10708/OMB control number: 0938-NEW)

BACKGROUND

The Centers for Medicare & Medicaid Services (CMS) is currently testing the Repetitive, Scheduled Non-Emergent Ambulance Transport (RSNAT) Prior Authorization Model, in limited states, under the authority of section 1115A of the Social Security Act (the Act). This model tests whether prior authorization of RSNAT services covered under Medicare Part B lowers program spending, while maintaining or improving the quality of care. Prior authorization is a process through which a request for provisional affirmation of coverage is submitted for review before the service is rendered to a beneficiary and before a claim is submitted for payment. It helps ensure that all relevant coverage, coding, and payment requirements are met before the service is rendered to the beneficiary and before the claim is submitted for payment. The RSNAT Prior Authorization Model began in the states of New Jersey, Pennsylvania, and South Carolina on December 1, 2014. Section 515(a) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114-10), added six states to the model as of January 1, 2016: North Carolina, Virginia, West Virginia, Maryland, Delaware, and the District of Columbia.

Medicare Coverage

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 supplier, before

[1] 42 CFR 410.40(d)(1).
[2] Program Memorandum Intermediaries/Carriers, Transmittal AB-03-106

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.

Model History

In the November 14, 2014 **Federal Register** (79 FR 68271), CMS 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 under the authority of section 1115A of the Act that established a process for requesting prior authorization for repetitive, scheduled non-emergent ambulance transport rendered by ambulance suppliers garaged in three 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 three states on December 1, 2017.

In the October 23, 2015 **Federal Register** (80 FR 64418), CMS published a notice titled "Medicare Program; Expansion of Prior Authorization of Repetitive Scheduled Non-emergent Ambulance Transports," which announced the inclusion of six additional states (Delaware, the District of Columbia, Maryland, North Carolina, West Virginia, and Virginia) in the RSNAT 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 six states began participation on January 1, 2016, and the model was originally scheduled to end in all nine model states on December 1, 2017.

In the December 12, 2017 **Federal Register** (82 FR 58400), CMS published a notice titled "Medicare Program; Extension of Prior Authorization for Repetitive Scheduled Non-Emergent Ambulance Transports," which announced a 1-year extension of the prior authorization model in all states through December 1, 2018.

In the December 4, 2018 **Federal Register** (83 FR 62577), CMS published a notice titled "Medicare Program; Extension of Prior Authorization for Repetitive Scheduled Non-Emergent Ambulance Transports," which announced a 1-year extension of the prior authorization model in all states through December 1, 2019.

In the September 16, 2019 **Federal Register** (84 FR 48620), CMS published a notice titled "Medicare Program; Extension of Prior Authorization for Repetitive Scheduled Non-Emergent Ambulance Transports," which announced a 1-year extension of the prior authorization model in all states through December 1, 2020.

[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.

Requirements for Nationwide Expansion

Section 515(b) of MACRA added paragraph (16) to section 1834(l) of the Act, which requires that, beginning January 1, 2017, the Secretary expand the model to all states if the model expansion meets certain statutory requirements for expanding models that are tested by the Center for Medicare and Medicaid Innovation (Innovation Center) under the authority of section 1115A of the Act. The expansion criteria, described in paragraphs (1) through (3) of section 1115A(c) of the Act, require that:

(1) the Secretary determines that such expansion is expected to—

(A) reduce spending under applicable title without reducing the quality of care; or

(B) improve the quality of patient care without increasing spending; and

(2) the Chief Actuary of the Centers for Medicare & Medicaid Services certifies that such expansion would reduce (or would not result in any increase in) net program spending under applicable titles; and

(3) the Secretary determines that such expansion would not deny or limit the coverage or provision of benefits under the applicable title for applicable individuals.

Because section 1834(l)(16) of the Act requires the Secretary to expand the RSNAT Prior Authorization Model to all States if it meets the statutory expansion criterial in 1115A(c)(1 through 3) of the Act, the exemption from Paperwork Reduction Act (PRA) process in 1115A(d)(3) is not applicable for the purposes of the nationwide expansion of this model. Therefore, in order to move forward with potential nationwide expansion, contingent on the Secretary's determination that the expansion criteria are met, CMS must complete the PRA approval process, as required by chapter 35 of title 44, United States Code. As part of the process for working towards potential expansion of the RSNAT Prior Authorization Model under section 1834(1)(16) of the Act, CMS is seeking approval for the collection of information under PRA.

National Model Design

The potential national model would follow the same design as the current RSNAT Prior Authorization Model, as described in the September 16, 2019 Federal Register (84 FR 48620) and may be implemented in multiple phases. If such a national model ultimately moves forward, the use of prior authorization would not create new clinical documentation requirements. Instead, it would require the same information that ambulance suppliers are already required to maintain to support Medicare payment. Prior authorization would allow ambulance suppliers to address coverage issues prior to furnishing services.

The prior authorization process would apply to the following Healthcare Common Procedure Coding System (HCPCS) 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 would not be needed for the mileage code, A0425, a prior authorization decision for A0426 or A0428 would apply to the associated mileage code.

Under such a potential national model, submitting a prior authorization request would be voluntary. However, an ambulance supplier or beneficiary would be encouraged to submit to the Medicare

Administrative Contractor (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 would 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, 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 would 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 would be provided to the ambulance 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 would make every effort to conduct a review and postmark the notification of their decision on the resubmitted request within 20 business days.

An ambulance 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 would make reasonable efforts to communicate a decision within 2 business days of receipt of all applicable Medicare-required documentation. As such a model would be for non-emergent services only, we would 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 could 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 would require an additional prior authorization request.

The MAC may consider an extended affirmation period for beneficiaries with a chronic condition that is deemed not likely to improve over time. The prior authorization decision, justified by the beneficiary's chronic condition, may affirm up to 120 round trips (which equates to 240 one-way trips) per prior authorization request in a 180-day period. The medical records must clearly indicate that the condition is chronic, and the MAC must have established through two previous prior authorization requests that the beneficiary's medical condition has not changed or has deteriorated from previous requests before allowing an extended affirmation period.

The following describes examples of various prior authorization scenarios:

- Scenario 1: When an ambulance 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 would send a provisional affirmative prior authorization decision to the ambulance supplier and the beneficiary.

When the subsequent claim is submitted to the MAC by the ambulance supplier, it would be linked to the prior authorization decision via the claims processing system, and the claim would be paid so long as all Medicare coding, billing, and coverage requirements are met. However, the claim could be denied for not meeting all claim processing requirements, such as a duplicate claim or a claim submitted 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 supplier or beneficiary submits a prior authorization request, but all relevant Medicare coverage requirements are not met, the MAC would send a non-affirmative prior authorization decision to the ambulance supplier and to the beneficiary advising them that Medicare will not pay for the service. The supplier or beneficiary may then resubmit the request with additional documentation showing that Medicare requirements have been met. Alternatively, an ambulance 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 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 supplier or beneficiary submits a prior authorization request with incomplete documentation, a detailed decision letter would be sent to the ambulance supplier and to the beneficiary, with an explanation of what information is missing. The ambulance supplier or beneficiary can rectify the error(s) and resubmit the prior authorization request with appropriate documentation.

● Scenario 4: If an ambulance 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 would be stopped for prepayment review and documentation would 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 would be denied, and all current policies and procedures regarding liability for payment would apply. The ambulance supplier or the beneficiary, or both, could appeal the claim denial if they believe the denial was inappropriate.

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

Only one prior authorization request per beneficiary per designated time period can be provisionally affirmed. If the initial ambulance 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 would be 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 suppliers are providing transports to the beneficiary during the same or overlapping time period, the prior authorization decision would only cover the ambulance supplier indicated in the provisionally affirmed prior authorization request. Any ambulance 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 would be subject to 100 percent prepayment medical review of those claims.

JUSTIFICATION

1. Need and Legal Basis

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 515(b) of MACRA added paragraph (16) to section 1834(l) of the Act, which requires that, beginning January 1, 2017, the Secretary expand the RSNAT Prior Authorization Model nationally to all states if model expansion meets certain statutory requirements for Innovation Center programs.

These requirements are described in paragraphs (1) through (3) of section 1115A(c) of the Act:

(1) the Secretary determines that such expansion is expected to—

(A) reduce spending under applicable title without reducing the quality of care; or

(B) improve the quality of patient care without increasing spending; and

(2) the Chief Actuary of the Centers for Medicare & Medicaid Services certifies that such expansion would reduce (or would not result in any increase in) net program spending under applicable titles; and

(3) the Secretary determines that such expansion would not deny or limit the coverage or provision of benefits under the applicable title for applicable individuals.

Pursuant to the authority in section 515(b) of MACRA, CMS is seeking to obtain the necessary approval under the PRA for the collection of information that would be needed for the RSNAT Prior Authorization Model, should the Secretary determine that it meets the criteria to be expanded.

2. Information Users and Use

If such a national model goes forward, the information required under this collection would be used to determine proper payment for repetitive, scheduled non-emergent ambulance transports. The information required in a prior authorization request package would include all medical documents and information to show that the number and level of transports requested are reasonable and necessary for the beneficiary and meet other Medicare requirements. If an ambulance supplier does not submit a prior authorization request by the fourth round trip in a 30-day period, and the claim is submitted to the MAC for payment, then the claim would be stopped for prepayment review and medical documentation would be requested.

Trained nurse reviewers from the MAC would review the information from the ambulance supplier to determine if the beneficiary meets Medicare's requirements for the transport and if the beneficiary needs the level of care requested. The MAC would also use the information to determine if the number of trips requested is reasonable and necessary.

3. Improved Information Techniques

Some of this collection of information could involve the use of electronic or other forms of information technology at the discretion of the submitter. Where available, ambulance suppliers may submit their prior authorization requests and/or other documentation through electronic means. CMS offers electronic submission of medical documentation (esMD)[i] and the MACs may provide an

electronic portal for ambulance suppliers to submit their documentation.

4. Duplication and Similar Information

Outside of the current RSNAT Prior Authorization Model operating in nine states, CMS does not perform prior authorization on RSNAT services. CMS as a whole does not collect this type of information in any existing format, including the medical documentation supporting the need for the transports. With the exception of basic identifying information such a beneficiary name, address, etc., there is no standard form or location where this information can be gathered.

5. Small Businesses

This collection would impact small businesses or other entities to the extent that those small businesses bill Medicare in a manner that triggers review under prior authorization. Ambulance suppliers regardless of size must maintain the necessary documentation to support their claims.

6. Less Frequent Collections

In a future expanded national model, if an ambulance supplier submits a claim for repetitive, scheduled non-emergent transports without a prior authorization decision on file, the claim would be stopped for prepayment review and the ambulance supplier would submit the documentation following receipt of an ADR. Since repetitive, scheduled ambulance transports are an area of vulnerability in Medicare, less frequent collection of information on these items under prior authorization would be imprudent and undermine the national model.

7. Special Circumstances

The frequency of the collection will vary depending on each beneficiary's ambulance transportation needs. Some respondents may need to report information more often than quarterly if they are transporting beneficiaries that require RSNAT services for longer than 60 days.

8. Federal Register Notice

A notice was published in the Federal Register on October 29, 2019 (84 FR 57875). Comments have been addressed in Appendix 1 - Response to Public Comments.

No additional outside consultation was sought.

9. Payments or Gifts to respondents

No payments or gifts will be given to respondents to encourage their response to any request for information under this control number.

10. Confidentiality

The MACs would safeguard all protected health information collected in accordance with Health Insurance Portability and Accountability Act (HIPAA) and Privacy Act standards as applicable.

Medicare contractors have procedures in place to ensure the protection of the health information

provided. The HIPAA Privacy Rule allows for the disclosure of health records for payment purposes.

11. Sensitive Questions

There are no questions of a sensitive nature associated with this information collection.

12. Burden Estimate

If the expanded national model moves forward, CMS anticipates that most submissions would be sent in through fax or by electronic means. The burden associated with such a national model is the time and effort necessary for the submitter to locate and obtain the supporting documentation for the Medicare claim and to forward the materials to the MAC for review. CMS expects that this information would generally be maintained by ambulance suppliers as a normal course of business and that this information would be readily available.

The documentation submitted would be the documentation from the medical record that supports medical necessity, the level of care requested, the number of transports requested, and demonstrates that the Medicare coverage requirements are met. Ambulance suppliers are currently required to maintain this information on file. The burden for maintaining this information has not been ccounted for previously.

CMS anticipates clerical staff would collect the information from the medical record and prepare it to be submitted for review. CMS estimates that the average time for office clerical activities associated with this task to be 30 minutes, equivalent to that for prepayment review (OMB Ctrl No 0938-0969).[1] An additional 3 hours of time is estimated for attending educational meetings and reviewing training documents. Average labor costs (including 100 percent fringe benefits) used to estimate the costs are calculated using data available from the Bureau of Labor Statistics. Based on Bureau of Labor Statistics found here (Miscellaneous Health care support occupations), we estimate an average hourly rate of $16.63 with a loaded rate of $33.26.

Table 1: Projected Burden for a Repetitive, Scheduled Non-Emergent Ambulance Transport Prior Authorization National Model

[1] The burden estimate reported here will not decrease the burden estimate or the number of prepayment reviews reported in OMB Ctrl No 0938-0960 titled *Medicare Fee-for-Service Early Review of Medical Records*. Under a national model, RSNAT claims that undergo prior authorization will not also undergo prepayment review. If a Medicare review contractor was conducting prepayment review of RSNAT claims prior to the model, they would shift their resources to other claim types.

Activity	Responses Per Year (i.e. number of reviewed claims)[2]	Time Per Response (hours) or Dollar Cost	Total Burden Per Year (hours)	Total Burden Costs Per Year Using Loaded Rate
Prior Authorization Fax and Electronic Submitted Requests	Submissions 118,524 Resubmissions 33,335	0.5 0.5	59,262 16,668	$1,971,054.12 $554,361.05
Prior Authorization Mailed in Requests	Submissions 50,796 Resubmissions 14,286	0.5 0.5	25,398 7,143	$844,737.48 $237,576.18
Prior Authorization-Education	Ambulance Suppliers 1,745[3]	3	5,235	$174,116.10
Prior Authorization Total			**113,706**	**$ 3,781,844.93**

The above estimate cost of $3.78 million is for the second year of a national model. Due to a proposed staggered implementation, year two would be the first full year of participation for all states. We expect the year 1 burden to be less than the subsequent years. This impact is allocated across ambulance suppliers nationally.

13. Capital Costs

CMS estimates the cost of mailing medical records to be $5. CMS offers esMD to ambulance

[2] The number of responses are based on the number of Medicare Fee-for-Service beneficiaries who received RSNAT services in calendar year 2017, with the following assumptions:

- Prior authorization requests will be submitted for 90 percent of beneficiaries receiving RSNAT services.
- Six initial prior authorization requests will be submitted per beneficiary per year, as a prior authorization request can be valid for up to 60 days.
- 25 percent of initial prior authorization requests will be non-affirmed and resubmitted.
- 70 percent of prior authorization requests will be submitted electronically and 30 percent will be submitted via mail.

[3] This number represents the number of ambulance suppliers that would potentially participate in educational trainings on the prior authorization process. As this number does not represent responses per year, it is not included in the total responses per year calculation.

suppliers who wish to use an electronic alternative for sending in medical documents. Additional information on esMD can be found at www.cms.gov/esMD. Some of the MACs also provide an electronic portal for ambulance suppliers to submit their documentation. Based on calendar year 2017 data, CMS estimates that under such a national model, at a minimum, there would be 50,796 initial prior authorization requests and responses to ADRs mailed during a year. In addition, CMS estimates there would be 14,286 resubmissions requests mailed following a non-affirmed decision. Therefore, the total mailing cost is estimated to be $325,410.

Activity	**Responses Per Year (i.e. number of reviewed claims)**	**Time Per Response (hours) or Dollar Cost**	**Total Costs Per Year**
Mailing Costs	Total Submissions 65,082	$5	$325,410

14. Costs to Federal Government

CMS estimates that the costs associated with performing reviews of repetitive, scheduled non-emergent ambulance transports would be approximately $39.1 million for the first year, dropping to $29.6 million per year in subsequent years.

Historical claims data was used to estimate the number of beneficiaries receiving repetitive, scheduled non-emergent ambulance transports in a year. Our cost estimate is based on the anticipated number of prior authorization requests, both initial and resubmissions, that would be submitted; the number of claims skipping prior authorization that would be medically reviewed through the prepayment review process; the number of potential appeals; and the cost of outreach and education to ambulance suppliers, physicians, and beneficiaries.

For subsequent years, we estimate the cost would decrease approximately $9.5 million from the initial year, based on experience attained from the RSNAT Prior Authorization Model currently operational in nine states. We assume there would be a 25% reduction in the number of beneficiaries receiving RSNAT services due to not meeting medical necessity requirements. We also assume the cost of outreach and education would decrease after the initial year.

15. Changes in Burden

This is a new collection. Therefore, there is no change in burden.

In the nine states currently under the model, ambulance suppliers submit an average of 23,050 prior authorization requests per year.

16. Publication or Tabulation

There are no plans to publish or tabulate the information collected.

17. Expiration Date

Each instrument displays the expiration date and OMB control number on the first page, top right corner.

[i] www.cms.gov/esMD