specified time period
- ○ Quantity of use over specified time period
- ○ Substance-related problems/symptom count scales

➢ **Functional Outcomes**

- ○ School performance and educational attainment
- ■ Attendance
- ■ Grades/academic performance
- ■ Graduation rates
- ■ Entering higher education (including trade schools)
- ○ Social relationships
- ■ Family functioning
- ■ Peer relationships

➢ **Harmful Consequences Associated With SUD**

- ○ Mental health outcomes
- ■ Suicidal ideation and behavior
- ○ Physical health outcomes
- • Mortality
- ■ All-cause
- ■ Drug-related, including fatal overdose
- ■ Morbidity
- ■ Injuries (non-fatal)
- • Infections
- ■ HIV
- ■ Hepatitis C
- ■ Other sexually transmitted infections
- ○ Legal outcomes
- • Arrests
- • Drunk or impaired driving
- • Contact with juvenile justice system

➢ **Adverse Effects of Intervention(s)**

- ○ Side effects of pharmacologic interventions
- ○ Loss of privacy/confidentiality
- ○ Stigmatization/discrimination
- ○ Iatrogenic effects of group therapy due to peer deviance
- ○ Other reported adverse effects ascribed to interventions

Study Designs and Information Sources

- • Published, peer reviewed articles and data from *clinicaltrials.gov*
- ○ Randomized controlled trials (including cross-over trials)
- ■ N ≥ 10 participants per study group
- ○ Large nonrandomized comparative studies with longitudinal follow-up
- ■ N ≥ 100 participants per study group
- ■ Must report multiple regression, other adjustment, matching, propensity scoring, or other method to account for confounding.
- ○ Single arm pharmacologic studies with at least 200 participants and longitudinal follow-up (to identify side-effects of medications)
- ○ We will summarize information from existing systematic reviews specific to treatment of alcohol SUD on college campuses
- ■ SR eligible if inclusion criteria for individual studies consistent with our PICOTS criteria for individual studies.

Exclusions

- ○ Case-control studies
- ○ Cross-sectional studies
- ○ Single-arm studies of behavioral interventions
- ○ Conference abstracts letters, and other non-peer reviewed reports

Timing

- • Any duration of treatment
- • Duration of follow-up of at least a month (but must be longitudinal with separation in time between intervention and outcomes)

Setting

- • Any setting, including (but not limited to) primary care, school, outpatient, emergency department, in-patient, intensive outpatient, partial hospitalization, intensive inpatient/residential, juvenile justice

Exclude: laboratory-based assessments.

Francis D. Chesley, Jr.,

Acting Deputy Director.

[FR Doc. 2018–26304 Filed 12–3–18; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[CDC–2018–0065; Docket Number NIOSH–317]

Final National Occupational Research Agenda for Oil and Gas Extraction

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: NIOSH announces the availability of the final *National Occupational Research Agenda for Oil and Gas Extraction*

DATES: The final document was published on November 27, 2018 on the CDC website.

ADDRESSES: The document may be obtained at the following link: *https://www.cdc.gov/nora/councils/oilgas/agenda.html*

FOR FURTHER INFORMATION CONTACT: Emily Novicki, M.A., M.P.H, (*NORACoordinator@cdc.gov*), National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Mailstop E–20, 1600 Clifton Road NE, Atlanta, GA 30329, phone (404) 498–2581 (not a toll free number).

SUPPLEMENTARY INFORMATION: On July 26, 2018, NIOSH published a request for public review in the **Federal Register** [83 FR 35485] of the draft version of the *National Occupational Research Agenda for Oil and Gas Extraction.* The single comment received expressed support.

Dated: November 29, 2018.

Frank J. Hearl,

Chief of Staff, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2018–26315 Filed 12–3–18; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–6063–N4]

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 begins on December 2, 2018 and ends on December 1, 2019.

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. 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, 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 prior 4 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 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), we 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 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 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), we 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.

II. Provisions of the Notice

This notice announces that the Medicare Prior Authorization Model for Repetitive Scheduled Non-Emergent Ambulance Transport is again 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 for an additional year while we continue to evaluate the model and determine if the model meets the statutory requirements for nationwide expansion under section 1834(l)(16) of the the Act, as added by section 515(b) of MACRA (Pub. L. 114–10). The model is currently scheduled to end in all states on December 1, 2019. Prior authorization will not be available for repetitive scheduled non-emergent ambulance transportation services furnished after that date.

We will continue to test whether prior authorization helps reduce expenditures, while maintaining or

[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.

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 will also continue our recent initiative to help find alternative resources for beneficiaries who do not meet the requirements of the Medicare repetitive scheduled non-emergent ambulance transport benefit. 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 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 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.

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.

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 have also recently implemented a process to help find alternative resources for beneficiaries who do not meet the requirements of the Medicare repetitive scheduled non-emergent ambulance transport benefit.

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 Act.

Dated: November 27, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2018–26334 Filed 11–30–18; 11:15 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–E–2801]

Determination of Regulatory Review Period for Purposes of Patent Extension; ASPIRE ASSIST

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for ASPIRE ASSIST and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that medical device.

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by February 4, 2019. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by June 3, 2019. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 4, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 3, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and