determinations of ITL situations; and surveyor documentation that includes a detailed deficiency statement that clearly supports the determination of manner and degree of non-compliance and the appropriate level of citation.

• Section 488.8(a)(2)(iv), to strengthen surveyor documentation to include sufficient detail to support the determination of the manner and degree of non-compliance and the appropriate level of deficiency citation.

• Section 489.13, related to the effective date of accreditation for facilities undergoing a survey for purposes of its initial participation in Medicare; to ensure the effective date of accreditation when deficiencies have been identified, and to ensure it is consistent with CMS regulatory requirements.

• To ensure comparability with the survey process requirements at § 488.26(d), TJC must have—

++ Updated its accreditation process policies to clarify that all surveys for TJC's Medicare ASC accreditation program are conducted unannounced.

++ Updated its accreditation process policies to ensure all required follow-up surveys for its Medicare ASC accreditation program meet the Medicare requirements.

++ Revised its accreditation process policies to clarify that the appropriate level of citation be made when an Immediate Threat to Health or Safety is identified.

++ Clarified its survey policies in the surveyor activity guide (SAG) to address how ''Special Issue Resolution'' is handled during surveys lasting only 1 day.

++ Updated its ASC accreditation process policies to clearly demonstrate that the policies are related to ASCs and not hospitals.

• Section 488.28(a), to include all documented observations of non-compliance and all internal, uncompleted Plans for Improvement (PFI) listed in the accredited ASC's ''Statement of Condition (SOC) to correct Life Safety Code Deficiencies'' into the survey report. In addition, TJC will provide CMS with rationale for each standard for which TJC has determined will not require a citation of non-compliance when a single observation has been made.

• Complied with section 1861(e)(9)(C) of the Act, to require that waiver and equivalency requests submitted by accredited organizations for Life Safety Code deficiencies that would result in unreasonable hardship for such a facility to resolve and would not jeopardize patient health or safety, be reviewed by TJC, and forwarded to CMS for approval, as appropriate.

• To demonstrate comparability with minimum eligibility requirements for Initial surveys, increased the minimum number of patients/volume of services from three patients served with one active at the time of survey, to ten patients served, with one active at the time of survey.

• To comply with TJS's own policies, TJS must—

++ Ensure its surveyors complete the ASC Infection Control Worksheet on every survey.

++ Ensure its surveyors observe at least one surgery during every survey.

++ Ensure that the minimum number of medical records have been reviewed on every survey.

++ Ensure that findings noted on the Infection Control Worksheet are integrated into the survey report findings.

B. Term of Approval

Based on our review and observations described in section III of this final notice, we approve TJC as a national accreditation organization for ASCs that request participation in the Medicare program, effective December 20, 2014 through December 20, 2020.

To verify TJC's continued compliance with the provisions of this final notice, we will conduct a follow-up corporate on-site visit and survey observation within 18 months of the date of publication of this final notice.

V. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Dated: November 5, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2014–27577 Filed 11–20–14; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–6064–N]

Medicare Program; Prior Authorization of Non-Emergent Hyperbaric Oxygen (HBO) Therapy

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

ACTION: Notice.

SUMMARY: This notice announces a 3-year Medicare Prior Authorization model for non-emergent hyperbaric oxygen therapy services in the states of Illinois, Michigan, and New Jersey where there have been high incidences of improper payments for these services.

DATES: The model will begin on March 1, 2015 in Michigan, New Jersey, and Illinois.

FOR FURTHER INFORMATION CONTACT: Jennifer McMullen, (410) 786–7635.

Questions regarding the Medicare Prior Authorization Model for Non-Emergent Hyperbaric Oxygen (HBO) Therapy should be sent to *HBOPA@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Hyperbaric Oxygen (HBO) therapy is a modality used for treatment of wounds in which the entire body is exposed to oxygen under increased atmospheric pressure. HBO therapy is covered as adjunctive therapy only after there have been no measurable signs of healing during at least 30 consecutive days of treatment with standard wound therapy, and must be used in addition to standard wound care. Wounds must be evaluated at least every 30 days during administration of HBO therapy. Continued treatment with HBO therapy is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment.

Medicare issued a National Coverage Determination (NCD) for HBO therapy in 2002, which lists clinical conditions for which HBO therapy is medically necessary and clinical conditions for which HBO therapy is not medically necessary, and therefore; not covered by Medicare. The NCD can be found in the Medicare National Coverage Determinations Manual (CMS Pub. No. 100–03), Chapter 1, Part 1, Section 20.29, and in the NCD database at *http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=37&bc=AiAAAAAAAgAAAA%3d%3d&*. In addition, some of

the Medicare Administrative Contractors (MACs) have Local Coverage Determinations (LCDs) that expand on the NCD.

In 2000, a report by the HHS Office of Inspector General [1] on hyperbaric oxygen therapy found the following:

- $14.2 million (of $49.9 million in allowed charges for outpatient hospital departments and physicians) was paid in error, either for beneficiaries who received treatments for non-covered conditions or when documentation did not adequately support HBO.
- An additional $4.9 million was paid for treatments deemed to be excessive.
- Lack of testing and treatment monitoring raised quality of care concerns.

Data from CMS' Chronic Condition Warehouse were used to determine state rankings based on average number of sessions per beneficiary. States were then ranked by expenditures. Illinois, Michigan, and New Jersey were selected as the initial states for the model because they ranked in the top three for average number of sessions per beneficiary.

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 this model, 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. 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. While these provisions are specific to durable medical equipment (DME) and physician services, we will waive any portion of these sections as well as any portion of 42 CFR 410.20(d) of the regulations, which implements section 1869(h) of the Act, that could be construed to limit our ability to conduct prior authorization.

[1] Office of Inspector General, Hyperbaric Oxygen Therapy, Its Use and Appropriateness, October 2000.

II. Provisions of the Notice

We plan to implement a 3-year Medicare Prior Authorization process for non-emergent HBO therapy rendered in 3 states (Illinois, Michigan, and New Jersey). These states were selected as the initial states for the model because of their high utilization and improper payment rates for this service. The model will begin in Michigan, New Jersey, and Illinois on March 1, 2015.

We plan to test whether prior authorization helps reduce expenditures, while maintaining or improving quality of care, using a model that would establish a prior authorization process for non-emergent HBO therapy to reduce utilization of services that do not comply with Medicare policy.

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

The use of prior authorization will not create new clinical documentation requirements. Instead, it will require the same information that is already required to support Medicare payment, just earlier in the process. Prior authorization allows facilities to address issues with claims prior to rendering services.

The prior authorization process under this model will be available for the following code for Medicare payment: C1300—Hyperbaric oxygen under pressure, full body chamber, per 30 minute interval.

Prior authorization is only needed for the facility payment part of the HBO therapy service. However, if a facility does not have prior authorization, or has a non-affirmed prior authorization, the associated physician claims with the following code will be subject to medical review: 99183—Physician attendance and supervision of hyperbaric oxygen, per session.

Of the 15 covered clinical conditions listed in the NCD, the following 6 will be available for prior authorization:

- Preparation and preservation of compromised skin grafts (not for primary management of wounds).
- Chronic refractory osteomyelitis, unresponsive to conventional medical and surgical management.
- Osteoradionecrosis as an adjunct to conventional treatment.
- Soft tissue radionecrosis as an adjunct to conventional treatment.
- Actinomycosis, only as an adjunct to conventional therapy when the disease process is refractory to antibiotics and surgical treatment.
- Diabetic wounds of the lower extremities in patients who meet the following three criteria:

++ Patient has Type I or Type II diabetes and a lower extremity wound that is due to diabetes.

++ Patient has a wound classified as Wagner grade III or higher.

++ Patient has failed an adequate course of wound therapy as defined in the NCD.

A provisional affirmative prior authorization decision, justified by the beneficiary's condition, may affirm up to 36 treatments in a 12-month period. 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. A provisional affirmative decision can be for all or part of the requested number of treatments. If additional treatments are needed, a subsequent prior authorization request must be submitted.

Prior to the start of the model, we will conduct (and thereafter will continue to conduct) outreach and education to facilities that provide HBO therapy, as well as to beneficiaries, through such methods as Open Door Forums, frequently asked questions (FAQs) on our Web site, other Web site postings, and educational materials issued by the Medicare Administrative Contractors (MACs). Additional information about the implementation of the prior authorization model is available on the CMS Web site at *http://go.cms.gov/PAHBO.*

Under this model prior authorization process, the facility or beneficiary will be encouraged to submit to the MAC a request for prior authorization along with all relevant documentation to support Medicare coverage of the HBO therapy. In order to be affirmed, the request for prior authorization must meet all applicable rules and policies, and any NCD and Local Coverage Determination (LCD) requirements for HBO therapy.

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 submitter of the prior

authorization request (and, upon request, to the beneficiary if he or she was not the original submitter). 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.

A facility 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 a non-emergent service only, we expect requests for expedited reviews to be extremely rare.

The following describes examples of various prior authorization scenarios:

- Scenario 1: When a facility 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 HBO therapy, the MAC will send a provisional affirmative prior authorization decision to the submitter (and, upon request, to the beneficiary if he or she was not the original submitter). When the claim is submitted to the MAC, it is linked to the prior authorization via the claims processing system and the claim is 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 being a duplicate claim or being for a date of service after a beneficiary's death.
- Scenario 2: When a facility 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 submitter (and, upon request, to the beneficiary if he or she was not the original submitter), advising them that Medicare will not pay for the service. The facility or beneficiary may then resubmit the request with documentation showing that Medicare requirements have been met. Alternatively, a facility could render the service, and submit a claim with a non-affirmative prior authorization tracking number, at which point the MAC would deny the claim. The facility or 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 a facility or beneficiary submits a prior authorization request with incomplete documentation, a detailed decision letter will be sent to the submitter (and, upon request, to the beneficiary if he or she was not the original submitter) with an explanation of what information is missing. The facility or beneficiary can rectify the situation and resubmit the prior authorization request with appropriate documentation.
- Scenario 4: When a facility renders a service that is subject to the prior authorization process to a beneficiary, and submits the claim 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 to be not 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 facility and/or beneficiary 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 facility, 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 facility cannot complete the total number of HBO treatments (for example, the initial facility closes or the beneficiary moves out of the 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 facilities are providing HBO treatments to the beneficiary during the same or overlapping time period, the prior authorization decision will only cover the facility indicated in the provisionally affirmed prior authorization request. Any facility submitting claims 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/PAHBO.*

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 (44 U.S.C. 35).

Authority: Section 1115A of the Social Security Act.

Dated: October 8, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2014–27578 Filed 11–20–14; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1464–N]

Medicare Program; Town Hall Meeting on FY 2016 Applications for New Medical Services and Technology Add-On Payments

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

ACTION: Notice of meeting.

SUMMARY: This notice announces a Town Hall meeting in accordance with section 1886(d)(5)(K)(viii) of the Social Security Act (the Act) to discuss fiscal year (FY) 2016 applications for add-on payments for new medical services and technologies under the hospital inpatient prospective payment systems (IPPS). Interested parties are invited to this meeting to present their comments, recommendations, and data regarding whether the FY 2016 new medical services and technologies applications meet the substantial clinical improvement criterion.

DATES: *Meeting Date:* The Town Hall Meeting announced in this notice will be held on Tuesday, February 3, 2015. The Town Hall Meeting will begin at 9:00 a.m. Eastern Standard Time (e.s.t.) and check-in will begin at 8:30 a.m. e.s.t.