the system and concerns related to the COVID–19 public health emergency response. Another commenter stated the commenter would like Medicare to cover acupuncturists in CAHs and other facilities.

While we appreciate the commenters' concerns, these comments are outside of the scope of this notice. We remain committed to improving the quality and safety of patients in all healthcare settings and providing oversight of all AOs.

V. Provisions of the Final Notice

A. Differences Between TJC's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements

We compared TJC's CAH requirements and survey process with the Medicare CoPs and survey process as outlined in the State Operations Manual (SOM). Our review and evaluation of TJC's CAH application were conducted as described in section III of this notice and yielded the following areas where, as of the date of this notice, TJC's has completed revising its standards and certification processes in order to:

- Meet the standard's requirements for all of the following regulations:

++ Section 485.604(a)(2), to clarify the requirements for education including a master's or doctoral level degree in a defined clinical area of nursing from an accredited educational institution.

++ Section 485.616(c)(4)(iv), to specify the requirement of an internal review of the distant-site physician's or practitioner's performance of the privileges at the CAH whose patients are receiving the telemedicine services.

++ Section 485.623(b)(1), to specify that all essential mechanical, electrical and patient care equipment is maintained in safe operating condition.

++ Section 485.635(b)(3), to include reference to State law within the standard for radiology services.

In addition to the standards review, CMS also reviewed TJC's comparable survey processes, which were conducted as described in section III of this notice, and yielded the following areas where, as of the date of this notice, TJC has completed revising its survey processes, in order to demonstrate that it uses survey processes that are comparable to state survey agency processes by:

- Revising TJC's surveyor guide to ensure a comprehensive review of environmental safety and life safety requirements are performed.
- Revising TJC's surveyor guide and survey processes to ensure compliance with the Medicare-conditions are assessed at each provider-based location where care is provided per CAH Appendix W of the SOM.
- Providing training and education to surveyors related to the use of open-ended questions during staff interviews to elicit information, consistent with chapter 2, section 2714 of the SOM.
- Revising the survey instructions and providing education to surveyors to conduct patient interviews. In accordance with CAH Appendix W-Task 3—Information Gathering/Investigation of the SOM, surveyors must observe the actual provision of care and services to patients and conduct patient interviews throughout the course of the survey.
- Review and assess TJC's surveyor time and resource allocations of the number of surveyors on site consistent with § 488.5(a)(5), § 488.5(a)(6) and § 488.5(a)(9) to ensure sufficient time is allotted to conduct all required survey activities.
- Provide additional training and education to surveyors on procedures related to investigation of ''immediate jeopardy'' situations in accordance with appendix Q-section VI of the SOM.
- Review and revise TJC's complaint investigation process, specifically to ensure the complainant (when not anonymous), receives an acknowledgement letter and closure letter, as outlined within chapter 5, sections 5010.2 and 5080.1 of the SOM.
- Review TJC's elements of performance and survey deficiency findings to ensure any deficiencies are appropriately correlated or matched with a Medicare condition, when appropriate, in accordance with § 488.5(a)(4)(ii).

B. Term of Approval

Based on our review and observations described in section III and section V of this notice, we approve TJC as a national AO for CAHs that request participation in the Medicare program. The decision announced in this final notice is effective November 21, 2023 through November 21, 2027 (4 years).

VI. 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. 3501 *et seq.*).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Vanessa Garcia who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Vanessa Garcia,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2023–17745 Filed 8–17–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Proposed Collection; Comment Request; Assessing ACL's American Indian, Alaskan Natives and Native Hawaiian Programs (OMB Control Number 0985–0059)

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) is providing an opportunity for the public to comment on the proposed collection of information listed above. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish a notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on a proposed extension without change information collection and solicits comments on the information collection requirements related to the project titled Assessing ACL's American Indian, Alaskan Natives and Native Hawaiian Programs (OMB Control Number 0985–0059).

DATES: Comments on the collection of information must be submitted electronically by 11:59 p.m. (EST) or postmarked by October 17, 2023.

ADDRESSES: Submit electronic comments on the collection of information to: Administration for Community Living at *evaluation@acl.hhs.gov.* Submit written comments on the collection of information to the Administration for Community Living, Washington, DC 20201, Attention: Administration for Community Living.

FOR FURTHER INFORMATION CONTACT: The Office of Performance and Evaluation, Administration for Community Living *evaluation@acl.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. A collection of information includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. The PRA requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, ACL is publishing a notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, ACL invites comments on our burden estimates or any other aspect of this collection of information, including:

(1) whether the proposed collection of information is necessary for the proper performance of ACL's functions, including whether the information will have practical utility;

(2) the accuracy of ACL's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used to determine burden estimates;

(3) ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) ways to minimize the burden of the collection of information on respondents, including using automated collection techniques when appropriate, and other forms of information technology.

The Administration for Community Living (ACL) is requesting approval for data collection associated with the project entitled Assessing ACL's American Indian, Alaska Natives, and Native Hawaiian Programs (Older Americans Act [OAA] Title VI; short title: *Assessment of the Title VI Programs*). OAA Title VI establishes grants to Native Americans for nutrition services, supportive services, and family caregiver support services. The purpose of Title VI is ''to promote the delivery of supportive services, including nutrition services, to American Indians, Alaskan Natives, and Native Hawaiians that are comparable to services provided under Title III'' (42 U.S.C. 3057), which provides nutrition, caregiver and supportive services to the broader U.S. population. Title VI is comprised of three parts; Part A provides nutrition and supportive services to American Indians and Alaska Natives, Part B provides nutrition and supportive services to Native Hawaiians, and Part C provides caregiver services to any programs that have Part A/B.

The previous data collection for this project entailed a series of interviews and focus groups with Title VI program staff, elders, and caregivers.

American Indian, Alaska Native, and Native Hawaiian (AI/AN/NH) populations experience significant health and socioeconomic disparities compared to the rest of the U.S. population. The AI/AN population has the highest rate of disabilities and the lowest life expectancy compared to the averages for the overall population (Centers for Disease Control and Prevention [CDC], 2008; Goins, Moss, Buchwald, & Guralnik, 2007). While 18% of the non-Hispanic white population is 65 years or older, just 8% of Native Hawaiians and 10% of the AI/AN population is 65 years or older (AoA, 2015). However, as overall life expectancy increases, the proportion of older AI/AN adults is expected to increase. By 2050, the percentage of non-Hispanic white adults is expected to decrease by 20%, while the population of older minority population adults, including AI/AN/NH, is expected to increase by 110% (AoA, 2015; CDC, 2013). For AI/AN populations, this translates to a 93% increase in the number of older adults.

In addition, the population aged 75 and older needing long-term care is expected to double by the year 2030 (AoA, 2015; CDC 2013; Goins et al., 2007).

In fiscal year 2023, ACL awarded 291 Title VI three-year grants to tribes/tribal organizations elders for the provision of nutrition and supportive services, and a portion of awardees also received funds for the Native American Caregiver Support Program. The Assessment of the Title VI Programs will examine the effects of the program on:

1. Older Indians, their families and caregivers
2. Tribal communities
3. Intergenerational connections in tribal communities
4. Management of the Title VI program

The Need for Continuous Assessment

Assessing and evaluating Title VI Programs is authorized under Section 206(a, c) of Title II of the OAA, which directs ACL to ''. . . measure and evaluate the impact of all programs authorized by this Act, their effectiveness in achieving stated goals in general, and in relation to their cost, their impact on related programs, their effectiveness in targeting for services under this Act unserved older individuals with greatest economic need (including low-income minority individuals and older individuals residing in rural areas) and unserved older individuals with greatest social need (including low-income minority individuals and older individuals residing in rural areas), and their structure and mechanisms for delivery of services, including, where appropriate, comparisons with appropriate control groups composed of persons who have not participated in such programs.''

Consistent with requirements of the Government Performance Results Modernization Act (GPRMA), ACL's Administration on Aging (AoA) integrates its strategic priorities and plans with performance measurement criteria. The AoA has three categories of performance measures: improve program efficiency, improve client outcomes, and improve effective targeting of vulnerable elders. Through continuous assessment, ACL seeks a better understanding of key programs, such as the programs under Title VI of the OAA for AI/AN/NH.

This project seeks to add a qualitative data collection activity to do follow-up interviews with grantees a to understand which components of the technical assistance they have received have been the most useful for them.

Exhibit 1 provides an overview of the process for assessing the Title VI Program data collection activity.

Exhibit 1

The Program Staff Follow-up Interviews will assess how the Title VI Programs have been utilizing and implementing the Technical Assistance they have received from the contractor around the practice of evaluation. Data will include how evaluation practice is being implemented and on what occurring basis, as well as perceptions of met and unmet needs around evaluation; and barriers to using evaluation. Up to 2 local staff (*e.g.,* program director and evaluation staff person) will participate in each interview. The interviews will be conducted via telephone in Year 4 with up to 12 evaluation grantees, for a maximum of 24 participants, and will take 60 minutes to complete. *See Attachment A (Title VI Program Staff Consent Form and Interview Guide).*

The proposed data collection tools may be found on the ACL website for review at *https://www.acl.gov/about-acl/public-input.*

ESTIMATED PROGRAM BURDEN

Respondent type	Form name	Number of annual respondents	Number of responses per respondent	Average burden per response (in hours)	Annual burden hours
Program director	Program staff follow-up interview guide.	80	1	1	80

Dated: August 14, 2023.

Alison Barkoff,

Senior official performing the duties of the Administrator and the Assistant Secretary for Aging.

[FR Doc. 2023–17788 Filed 8–17–23; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–P–1549]

Determination That BORTEZOMIB (Bortezomib) Solution, 2.5 Milligrams/Milliliter and 3.5 Milligrams/1.4 Milliliter (2.5 Milligrams/Milliliter), Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) has determined that BORTEZOMIB (bortezomib) solution, 2.5 milligrams (mg)/milliliter (mL) and 3.5 mg/1.4 mL (2.5 mg/mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for BORTEZOMIB (bortezomib) solution, 2.5 mg/mL and 3.5 mg/1.4 mL (2.5 mg/mL), if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Donna Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6213, Silver Spring, MD 20993–0002, 301–796–3600, *Donna.Tran@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

BORTEZOMIB (bortezomib) solution, 2.5 mg/mL and 3.5 mg/1.4 mL (2.5 mg/mL), is the subject of NDA 215441, held by Accord Healthcare Inc., and initially approved on July 26, 2022. BORTEZOMIB is indicated for the treatment of adult patients with multiple myeloma or mantle cell lymphoma.

In a letter dated February 8, 2023, Accord Healthcare Inc. notified FDA that BORTEZOMIB (bortezomib) solution, 2.5 mg/mL and 3.5 mg/1.4 mL (2.5 mg/mL), was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Qilu Pharmaceutical (Hainan) Co., Ltd. submitted a citizen petition dated April 19, 2023 (Docket No. FDA–2023–P–1549), under 21 CFR 10.30, requesting that the Agency determine whether BORTEZOMIB (bortezomib) solution, 2.5 mg/mL and 3.5 mg/1.4 mL (2.5 mg/mL), was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that BORTEZOMIB (bortezomib) solution, 2.5 mg/mL and 3.5 mg/1.4 mL (2.5 mg/mL), was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that BORTEZOMIB (bortezomib) solution, 2.5 mg/mL and 3.5 mg/1.4 mL (2.5 mg/mL), was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of BORTEZOMIB (bortezomib) solution, 2.5 mg/mL and 3.5 mg/1.4 mL (2.5 mg/mL), from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list BORTEZOMIB (bortezomib) solution, 2.5 mg/mL and 3.5 mg/1.4 mL (2.5 mg/mL), in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to these drug products may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: August 14, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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