• the revised version of ''Asb2 regulates the activity of SCF E3 ubiquitin ligases by antagonizing CAND1-mediated exchange of F-box proteins,'' submitted to *Molecular Cell* on September 29, 2014; hereafter referred to as the ''revised *Molecular Cell* manuscript

• grant application CA189216–01 submitted to the National Cancer Institute (NCI), NIH; hereafter referred to as the ''original NCI grant application''

• grant application CA189216–01A1 submitted to NCI, NIH; hereafter referred to as the ''revised NCI grant application''

ORI found that Respondent knowingly falsified and/or fabricated Western blot gel images by duplication, reuse and relabeling, and/or alteration through contrast, rotation, and/or scale of the images.

Specifically, Respondent included falsified images in all of the figures (Figures 1–6 and S1–5) in the original *Molecular Cell* manuscript, all of the figures (Figures 1–6 and S1–7) in the revised

Molecular Cell manuscript, Figures 2–4, 9, and 11 in the original NCI grant application, and Figures 3–5, 10, and 11 in the revised NCI grant application.

Dr. Kang has entered into a Voluntary Settlement Agreement (Agreement) and has voluntarily agreed for a period of three (3) years, beginning on December 23, 2014:

(1) To have his research supervised; Respondent agreed to ensure that prior to the submission of an application for U.S. Public Health Service (PHS) support for a research project on which the Respondent's participation is proposed and prior to Respondent's participation in any capacity on PHS-supported research, the institution employing him must submit a plan for supervision of his duties to ORI for approval; the plan for supervision must be designed to ensure the scientific integrity of Respondent's research contribution; Respondent agreed that he will not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI; Respondent agreed to maintain responsibility for compliance with the agreed upon plan for supervision;

(2) that any institution employing him must submit, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract; and

(3) to exclude himself voluntarily from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

FOR FURTHER INFORMATION CONTACT: Acting Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453–8200.

Donald Wright,

Acting Director, Office of Research Integrity.

[FR Doc. 2015–00802 Filed 1–16–15; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary; Office of Medicare Hearings and Appeals; Statement of Organization, Functions, and Delegations of Authority

Part A, Office of the Secretary, Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services, is being amended at Chapter AK, Office of Medicare Hearings and Appeals (OMHA), as last amended at 70 FR 36386–36387, dated June 23, 2005, and most recently at 76 FR 19995 (Apr. 11, 2011) as follows:

I. Under Section AK.10, Organization, delete the bullets and sub-bullets after the phrase, ''OMHA consists of the following components,'' and replace with the following:

• Medicare Hearings and Appeals Chief Judge's Office (CJO) (Headquarters Office)

— Office of Operations

— Office of Programs

• Medicare Hearings and Appeals Field Offices

II. Under Section AK.20, Functions, Paragraph B, replace ''Medicare Hearings and Appeals Field Offices (AKB1–4)'' with ''Medicare Hearings and Appeals Field Offices.''

III. Under Section AK.20, Functions, Paragraph B, ''Medicare Hearings and Appeals Field Offices,'' replace all references to the ''Managing Administrative Law Judge (MALJ)'' with ''Associate Chief Administrative Law Judge (ACALJ).''

Dated: January 13, 2015.

E.J. Holland, Jr.,

Assistant Secretary for Administration (ASA).

[FR Doc. 2015–00743 Filed 1–16–15; 8:45 am]

BILLING CODE 4150–24–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3303–FN]

Medicare and Medicaid Programs; Continued Approval of the Accreditation Commission for Health Care, Inc.; Home Health Agency Accreditation Program

AGENCY: Centers for Medicare and Medicaid Services, HHS.

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve the Accreditation Commission for Health Care, Inc., (ACHC) for continued recognition as a national accrediting organization for home health agencies (HHAs) that wish to participate in the Medicare or Medicaid programs. An HHA that participates in Medicaid must also meet the Medicare conditions for participation (CoPs) as required under 42 CFR 488.6(b).

DATES: This final notice is effective February 24, 2015 through February 24, 2021.

FOR FURTHER INFORMATION CONTACT: Cindy Melanson, (410) 786–0310, or Patricia Chmielewski, (410) 786–6899.

SUPPLEMENTARY INFORMATION:

I. Background

A healthcare provider may enter into an agreement with Medicare to participate in the program as a HHA provided certain requirements are met. Sections 1861(o) and 1891 of the Social Security Act (the Act), establish distinct criteria for facilities seeking designation as a HHA. Regulations concerning Medicare provider agreements in general are at 42 CFR part 489 and those pertaining to the survey and certification for Medicare participation of providers and certain types of suppliers are at part 488. The regulations at part 484 specify the specific conditions that a provider must meet to participate in the Medicare program as an HHA.

Generally, to enter into a Medicare provider agreement, a facility must first be certified as complying with the conditions set forth in part 484 and recommended to us for participation by

a state survey agency. Thereafter, the HHA is subject to periodic surveys by a state survey agency to determine whether it continues to meet these conditions. However, there is an alternative to certification surveys by state agencies. Accreditation by a nationally recognized Medicare accreditation program approved by us may substitute for both initial and ongoing state review.

Section 1865(a)(1) of the Act provides that, if the Secretary of the Department of Health and Human Services, (the Secretary) finds that accreditation of a provider entity by an approved national accrediting organization meets or exceeds all applicable Medicare conditions, we may treat the provider entity as having met those conditions, that is, we may ''deem'' the provider entity to be in compliance. Accreditation by an accrediting organization is voluntary and is not required for Medicare participation.

Part 488, subpart A, implements the provisions of section 1865 and requires that a national accrediting organization applying for approval of its Medicare accreditation program must provide us with reasonable assurance that the accrediting organization requires its accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the approval of accrediting organizations are set forth at § 488.4 and § 488.8(d)(3). The regulations at § 488.8(d)(3) require an accrediting organization to reapply for continued approval of its Medicare accreditation program every 6 years or sooner as determined by us. ACHC's current term of approval as a recognized Medicare accreditation program for HHAs expires February 24, 2015.

II. Application Approval Process

Section 1865(a)(3)(A) of the Act provides a statutory timetable to ensure that our review of applications for CMS-approval of an accreditation program is conducted in a timely manner. The Act provides us with 210 days after the date of receipt of a complete application, with any documentation necessary to make the determination, to complete our survey activities and application process. Within 60 days after receiving a complete application, we must publish a notice in the **Federal Register** that identifies the national accrediting body making the request, describes the request, and provides no less than a 30-day public comment period. At the end of the 210-day period, we must publish a notice in the **Federal Register** approving or denying the application.

III. Provisions of the Proposed Notice

In the August 22, 2014 **Federal Register** (79 FR 49777), we published a proposed notice announcing ACHC's request for continued approval of its Medicare HHA accreditation program. In that notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and in our regulations at § 488.4 and § 488.8, we conducted a review of ACHC's Medicare HHA accreditation application in accordance with the criteria specified by our regulations, which include, but are not limited to the following:

- An onsite administrative review of ACHC's: (1) Corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its HHA surveyors; (4) ability to investigate and respond appropriately to complaints against accredited HHAs; and, (5) survey review and decision-making process for accreditation.
- The comparison of ACHC's Medicare accreditation program standards to our current Medicare HHA CoPs.
- A documentation review of ACHC's survey process to:

++ Determine the composition of the survey team, surveyor qualifications, and ACHC's ability to provide continuing surveyor training.

++ Compare ACHC's processes to those we require of state survey agencies, including periodic resurvey and the ability to investigate and respond appropriately to complaints against accredited HHAs.

++ Evaluate ACHC's procedures for monitoring HHAs it has found to be out of compliance with ACHC's program requirements. (This pertains only to monitoring procedures when ACHC identifies non-compliance. If noncompliance is identified by a state survey agency through a validation survey, the state survey agency monitors corrections as specified at § 488.7(d).)

++ Assess ACHC's ability to report deficiencies to the surveyed HHA and respond to the HHA's plan of correction in a timely manner.

++ Establish ACHC's ability to provide us with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

++ Determine the adequacy of ACHC's staff and other resources.

++ Confirm ACHC's ability to provide adequate funding for performing required surveys.

++ Confirm ACHC's policies with respect to surveys being unannounced.

++ Obtain ACHC's agreement to provide us with a copy of the most current accreditation survey together with any other information related to the survey as we may require, including corrective action plans.

In accordance with section 1865(a)(3)(A) of the Act, the August 22, 2014 proposed notice also solicited public comments regarding whether ACHC's requirements met or exceeded the Medicare CoPs for HHAs. No comments were received in response to our proposed notice.

IV. Provisions of the Final Notice

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

We compared ACHC's HHA accreditation requirements and survey process with the Medicare CoPs of 42 CFR part 484, and the survey and certification process requirements of parts 488 and 489. Our review and evaluation of ACHC's HHA application, which were conducted as described in section III of this final notice, yielded the following areas where, as of the date of this notice, ACHC has completed revising its standards and certification processes to meet the requirements at:

- Section 1891(c)(2)(A) of the Act, to ensure all renewal surveys are conducted within 36 months of the last survey end date.
- § 484.10(c)(2), to address the patient's right to participate in the planning of care.
- § 484.14(e), to ensure personnel records include qualifications and current licensure.
- § 488.8(a)(2)(v), to ensure data submitted in CMS' Accrediting Organization System for Storing User Recorded Experiences (ASSURE) database is complete and accurate.
- § 489.3, to ensure situations that rise to the level of immediate jeopardy (IJ) are cited at the condition level.

B. Term of Approval

Based on our review and observations described in section IV of this final notice, we have determined that the ACHC accreditation program requirements meet or exceed our requirements. Therefore, we approve the ACHC as a national accreditation organization for HHAs that request participation in the Medicare program, effective February 24, 2015 through February 24, 2021.

V. Collection of Information Requirements

This document does not impose information collection and

recordkeeping requirements. Consequently, it 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).

Dated: January 9, 2015.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2015–00699 Filed 1–16–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–0025]

Medical Device Accessories: Defining Accessories and Classification Pathway for New Accessory Types; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Medical Device Accessories: Defining Accessories and Classification Pathway for New Accessory Types.'' This draft document provides proposed guidance to industry and FDA staff about the regulation of accessories in medical devices. The guidance explains what FDA considers to be an ''accessory,'' outlines how the risk-based framework for the classification of devices applies to accessories, and describes the use of the *de novo* classification process for the classification of new types of accessories. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 20, 2015. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by March 23, 2015. See section IV of this document, the ''Paperwork Reduction Act of 1995.''

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Medical Device Accessories: Defining Accessories and Classification Pathway for New Accessory Types'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the draft guidance or the information collection to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Sugato De, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5435, Silver Spring, MD 20993–0002, 301–796–6270 or Stephen Ripley, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance document is intended to provide guidance to industry and FDA staff about the regulation of accessories to other medical devices. In doing so, this guidance document explains what FDA considers to be an ''accessory'' and outlines how the risk-based framework for the classification of devices applies to accessories. In addition, this guidance describes use of the *de novo* classification process to classify new types of accessory devices under Section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(2)) based on risk and the ability of general and special controls to assure safety and effectiveness.

For the purposes of this guidance document, FDA considers an ''accessory'' as a medical device that is intended to support, supplement, and/or augment the performance of one or more medical devices. In practice, the distinctions among devices that support, supplement, and/or augment parent devices are subtle and many devices that we would consider to be an accessory may do more than one of these things. Thus, if the device is intended to support, supplement, and/or augment the performance of one or more parent devices, we intend to consider the device as an accessory.

Once a specific article has been determined to be an accessory, the guidance document describes how the accessory is classified based on its risks when used as intended with the intended parent device(s). In practice, FDA may classify individual accessories either by inclusion in the classification regulation of the parent device (either via a premarket submission or via express inclusion in the language of the regulation or order) or via development of a unique, separate classification regulation or order for the accessory.

For accessories of a new type, the guidance outlines the use of the *de novo* process for classification. This process provides a pathway to class I or class II classification for accessory devices for which general controls, or general and special controls, provide a reasonable assurance of safety and effectiveness, but for which there are no legally marketed predicate device.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the regulation of medical device accessories. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*. Guidance documents are also available at *http://www.regulations.gov*. Persons unable to download an electronic copy of ''Medical Device Accessories: Defining Accessories and Classification Pathway for New Accessory Types'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1770 to identify the guidance you are requesting.