

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Food Workers	EHS-Net Food Worker Recruiting Screener, Informed Consent and Interview.	4,000	1	20/60	1,333
HD staff	EHS-Net Restaurant Observation	400	1	30/60	200
Total	1,777

Leroy A. Richardson,
 Chief, Information Collection Review Office,
 Office of Scientific Integrity, Office of the
 Associate Director for Science, Office of the
 Director, Centers for Disease Control and
 Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3357-PN]

Medicare and Medicaid Program; Application From DNV GL—Healthcare (DNV GL) for Continued Approval of Its Hospital Accreditation Program

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

ACTION: Notice with request for comment.

SUMMARY: This proposed notice acknowledges the receipt of an application from DNV GL—Healthcare for continued recognition as a national accrediting organization for hospitals that wish to participate in the Medicare or Medicaid programs. The statute requires that we publish, within 60 days of receipt of an organization’s complete application, a notice that identifies the national accrediting body making the request, describes the nature of the request, and provides at least a 30-day public comment period.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on May 17, 2018.

ADDRESSES: In commenting, refer to file code CMS-3357-PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the “Submit a comment” instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-3357-PN, P.O. Box 8016, Baltimore, MD 21244-8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-3357-PN, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Karena Meushaw (410) 786-6609, Patricia Chmielewski, (410) 786-6899 or Monda Shaver, (410) 786-3410.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that website to view public comments.

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services from a hospital, provided that certain requirements are met. Section 1861(e) of the Social Security Act (the Act), establishes distinct criteria for facilities seeking designation as a hospital. Regulations concerning provider agreements are at 42 CFR part

489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488. The regulations at 42 CFR part 482 specify the minimum conditions that a hospital must meet to participate in the Medicare program.

Generally, to enter into an agreement, a hospital must first be certified by a state survey agency as complying with the conditions or requirements set forth in part 482 of our regulations. Thereafter, the hospital is subject to regular surveys by a state survey agency to determine whether it continues to meet these requirements. There is an alternative; however, to surveys by state agencies.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national accrediting organization that all applicable Medicare conditions are met or exceeded, we may deem those provider entities as having met the requirements. Accreditation by an accrediting organization is voluntary and is not required for Medicare participation.

If an accrediting organization is recognized by the Secretary of the Department of Health and Human Services (the Secretary) as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body’s approved program may be deemed to meet the Medicare conditions. A national accrediting organization applying for approval of its accreditation program under part 488, subpart A, must provide the Centers for Medicare and Medicaid Services (CMS) with reasonable assurance that the accrediting organization requires the 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 § 488.5. The regulations at § 488.5(e)(2)(i) require accrediting organizations to reapply for continued approval of its accreditation program every 6 years or

sooner as determined by CMS. DNV GL—Healthcare (DNV GL) current term of approval for their hospital accreditation program expires September 26, 2018.

II. Provisions of the Proposed Notice

A. Approval of Deeming Organizations

Section 1865(a)(2) of the Act and our regulations at § 488.5 require that our findings concerning review and approval of a national accrediting organization's requirements consider, among other factors, the applying accrediting organization's requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or requirements; and ability to provide us with the necessary data for validation.

Section 1865(a)(3)(A) of the Act further requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. We have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

The purpose of this proposed notice is to inform the public of DNV GL's request for continued approval of its hospital accreditation program. This notice also solicits public comment on whether DNV GL's requirements meet or exceed the Medicare conditions of participation (CoPs) for hospitals.

B. Evaluation of Deeming Authority Request

DNV GL submitted all the necessary materials to enable us to make a determination concerning its request for continued approval of its hospital accreditation program. This application was determined to be complete on February 28, 2018. Under section 1865(a)(2) of the Act and our regulations at § 488.5 (Application and re-application procedures for national accrediting organizations), our review and evaluation of DNV GL will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of DNV GL's standards for hospitals as compared with CMS' hospital CoPs.
- DNV GL's survey process to determine the following:
 - ++ The composition of the survey team, surveyor qualifications, and the

ability of the organization to provide continuing surveyor training.

++ The comparability of DNV GL's processes to those of state agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

++ DNV GL's processes and procedures for monitoring a hospital found out of compliance with the DNV GL's program requirements. These monitoring procedures are used only when the DNV GL identifies noncompliance. If noncompliance is identified through validation reviews or complaint surveys, the state survey agency monitors corrections as specified at § 488.9(c).

++ DNV GL's capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

++ DNV GL's capacity to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

++ The adequacy of DNV GL's staff and other resources, and its financial viability.

++ DNV GL's capacity to adequately fund required surveys.

++ DNV GL's policies with respect to whether surveys are announced or unannounced, to assure that surveys are unannounced.

++ DNV GL's agreement to provide CMS 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).

C. Notice Upon Completion of Evaluation

Upon completion of our evaluation, including evaluation of public comments received as a result of this notice, we will publish a final notice in the **Federal Register** announcing the result of our evaluation.

III. 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).

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not

able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Dated: April 9, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-2294]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Evaluation of the Fresh Empire Campaign on Tobacco

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by May 17, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0788. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed