

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.*

[FR Doc. 2018-08007 Filed 4-16-18; 8:45 am]

BILLING CODE 4163-18-P

**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](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