

Cruise Lines International Association (“CLIA”), the leading industry trade group. To that end, CLIA members and certain individual cruise lines have voluntarily taken steps to try to mitigate the impact of the spread of COVID-19. On March 13, 2020, CLIA and their associated members announced that all member cruise lines would voluntarily suspend cruise ship operations from U.S. ports of call for 30 days as public health officials and the Federal government continue to address COVID-19. The Federal government recognizes the enormity and importance of this action taken by CLIA and the commitment it demonstrates to protecting the health of both cruise ship passengers and the public at large. Following the example set by CLIA members, additional cruise lines have also voluntarily suspended operations from U.S. ports of call. Although the CLIA members and the additional cruise lines implementing a voluntary suspension of operations represent a large majority of the cruise industry, not all cruise lines or ships have announced a voluntary suspension of operations or that they will follow the important example set by CLIA members. This Order is intended to cover and specifically apply to those cruise lines or ships that do not undertake a voluntary suspension of operations. As a result, this Order specifically excludes from applicability any cruise line or ship that voluntarily suspends operations for the period of this Order, as CLIA members have done.

Findings and Immediate Action

Accordingly, and consistent with 42 CFR 71.32(b), the Director of CDC (“Director”) finds evidence to support a reasonable belief that cruise ships are or may become infected or contaminated with a quarantinable communicable disease.⁵ This reasonable belief is based on information from epidemiologic and other data regarding the nature and transmission of COVID-19 on cruise ships from the recent outbreaks onboard the Diamond Princess, Grand Princess, and other cruise ships. As a result, cruise ship passengers may be infected with or exposed to COVID-19 by virtue of having been onboard a cruise ship at a time when cases of COVID-19 are being reported in significant numbers globally and specifically on cruise ships, when testing is available. The Director also finds that cruise ship travel may exacerbate the global spread

of COVID-19. The scope of this pandemic is inherently and necessarily a problem that is international and interstate in nature, and cannot be controlled sufficiently by the cruise ship industry or individual state or local health authorities. Accordingly, under 42 CFR 70.2, the Director determines that measures taken or likely to be taken by state and local health authorities regarding COVID-19 onboard cruise ships are inadequate to prevent the further interstate spread of the disease.

The Director further determines that this Order provides public health authorities, in concert with the cruise ship industry, the necessary pause in operations to develop and implement an appropriate and robust plan to prevent and mitigate the spread of COVID-19, and acts to prevent the spread of the disease and ensure cruise ship passenger and crew health.

Therefore, in accordance with Sections 361 and 365 of the Public Health Service Act (42 U.S.C. 264, 268) and 42 CFR 70.2, 71.32(b), for all cruise ships not voluntarily suspending operations for the period described below, it is *ordered*:

1. Cruise ship operators shall be allowed to disembark passengers and crew members at ports or stations only as directed by the United States Coast Guard (USCG), in consultation with HHS/CDC personnel and, as appropriate, as coordinated with Federal, state, and local authorities.

2. Cruise ship operators shall not reembark any crew member, except as approved by USCG, in consultation with HHS/CDC personnel, until further notice.

3. Cruise ship operators shall not embark any new passengers or crew, except as approved by USCG, or other Federal authorities as appropriate, in consultation with HHS/CDC personnel.

4. Cruise ship operators shall not commence or continue operations (e.g., shifting berths, moving to anchor, or discharging waste), except as approved by USCG, in consultation with HHS/CDC personnel, until further notice.

5. While in port, the cruise ship operator shall observe health precautions as directed by HHS/CDC personnel.

6. The cruise ship operator shall comply with all HHS/CDC, USCG, and other Federal agency instructions to follow CDC recommendations and guidance for any public health actions relating to passengers, crew, ship, or any article or thing on board the ship, as needed, including by making ship’s manifests and logs available and collecting any specimens for COVID-19 testing.

7. This order does not prevent the periodic reboarding of the ship by HHS/CDC personnel and/or USCG and/or other Federal, state, or local agencies or the taking on of ships’ stores and provisions under the supervision of HHS/CDC personnel and/or USCG.

8. This order does not prevent the ship from taking actions necessary to maintain the seaworthiness or safety of the ship, or the safety of harbor conditions, such as movement to establish safe anchorage, or as otherwise directed by USCG personnel.

CDC may modify this order by an updated publication in the **Federal Register** or by posting an advisory to follow at www.cdc.gov.

Authority

The authority for these orders is Sections 361 and 365 of the Public Health Service Act (42 U.S.C. 264, 268) and 42 CFR 70.2, 71.32(b).

Dated: March 19, 2020.

Robert R. Redfield,

Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10468, CMS-10418, CMS-10488, CMS-R-290 and CMS-10525]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS’ intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency’s functions,

⁵ COVID-19 is a communicable disease for which quarantine is authorized under Section 361 of the Public Health Service Act (42 U.S.C. 264) and 42 CFR 70.1, 71.1, as listed in Executive Order 13295, as amended by Executive Orders 13375 and 13674.

the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by May 26, 2020.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for “Comment or Submission” or “More Search Options” to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS’ website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection’s supporting statement and associated materials (see **ADDRESSES**).

ADDRESSES:

CMS-10468 Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes, and Premiums and Cost Sharing; Exchanges: Eligibility and Enrollment

CMS-10418 Annual MLR and Rebate Calculation Report and MLR Rebate Notices

CMS-10488 Consumer Experience Survey Data Collection

CMS-R-290 Medicare Program: Procedures for Making National Coverage Decisions

CMS-10525 PACE Quality Data Monitoring and Reporting

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term “collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes, and Premiums and Cost Sharing; Exchanges: Eligibility and Enrollment; *Use:* The Exchanges, which became operational on January 1, 2014, enhanced competition in the health insurance market, expanded access to affordable health insurance for millions of Americans, and provided consumers with a place to easily compare and shop for health insurance coverage. The reporting requirements and data collection in Medicaid, Children’s Health Insurance Programs, and Exchanges: Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes, and Premiums and Cost Sharing; Exchanges: Eligibility and Enrollment (CMS-2334-F) address: (1) Standards related to notices, (2) procedures for the verification of enrollment in an eligible employer-sponsored plan and eligibility for qualifying coverage in an eligible employer-sponsored plan; and (3) other eligibility and enrollment provisions to provide detail necessary for state implementation. The submission seeks OMB approval of the information

collection requirements associated with selected provisions in 45 CFR parts 155, 156 and 157. *Form Number:* CMS-10468 (OMB control number: 0938-1207); *Frequency:* Annually; *Affected Public:* Individuals, Households and Private Sector; *Number of Respondents:* 1,522; *Total Annual Responses:* 9,533; *Total Annual Hours:* 103,710. For policy questions regarding this collection contact Anne Pesto at 443-844-9966.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Annual MLR and Rebate Calculation Report and MLR Rebate Notices; *Use:* Under Section 2718 of the Affordable Care Act and implementing regulation at 45 CFR part 158, a health insurance issuer (issuer) offering group or individual health insurance coverage must submit a report to the Secretary concerning the amount the issuer spends each year on claims, quality improvement expenses, non-claims costs, Federal and State taxes and licensing and regulatory fees, the amount of earned premium, and beginning with the 2014 reporting year, the amounts related to the transitional reinsurance, risk corridors, and risk adjustment programs established under sections 1341, 1342, and 1343, respectively, of the Affordable Care Act. An issuer must provide an annual rebate if the amount it spends on certain costs compared to its premium revenue (excluding Federal and States taxes and licensing and regulatory fees) does not meet a certain ratio, referred to as the medical loss ratio (MLR). Each issuer is required to submit annually MLR data, including information about any rebates it must provide, on a form prescribed by CMS, for each State in which the issuer conducts business. Each issuer is also required to provide a rebate notice to each policyholder that is owed a rebate and each subscriber of policyholders that are owed a rebate for any given MLR reporting year. Additionally, each issuer is required to maintain for a period of seven years all documents, records and other evidence that support the data included in each issuer’s annual report to the Secretary.

Based upon CMS’ experience in the MLR data collection and evaluation process, CMS is updating its annual burden hour estimates to reflect the actual numbers of submissions, rebates and rebate notices.

The 2019 MLR Reporting Form and Instructions reflect changes for the 2018 reporting year and beyond. The 2019 MLR Reporting Form and instructions are also modified to eliminate the reporting elements that were required under the risk corridors data submission

requirements in 45 CFR 153.530 for the 2014 through 2016 benefit years. For 2019, it is expected that issuers will submit fewer reports and on average, send fewer notices and rebate checks in the mail to policyholders and subscribers, which will reduce burden on issuers. In addition, issuers of qualified health plans will no longer have to submit on the annual report the data for the risk corridors program established under section 1342 of the Patient Protection and Affordable Care Act. *Form Number:* CMS–10418 (OMB control number: 0938–1164); *Frequency:* Annually; *Affected Public:* Private Sector, Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 494; *Number of Responses:* 1,896; *Total Annual Hours:* 232,427. For policy questions regarding this collection contact Stephanie Watson at 301–492–4238.

3. Type of Information Collection Request: Renewal of a currently approved collection; *Title of Information Collection:* Consumer Experience Survey Data Collection; *Use:* Section 1311(c)(4) of the Affordable Care Act requires the Department of Health and Human Services (HHS) to develop an enrollee satisfaction survey system that assesses consumer experience with qualified health plans (QHPs) offered through an Exchange. It also requires public display of enrollee satisfaction information by the Exchange to allow individuals to easily compare enrollee satisfaction levels between comparable plans. HHS established the QHP Enrollee Experience Survey (QHP Enrollee Survey) to assess consumer experience with the QHPs offered through the Marketplaces. The survey includes topics to assess consumer experience with the health care system such as communication skills of providers and ease of access to health care services. CMS developed the survey using the Consumer Assessment of Health Providers and Systems (CAHPS®) principles (<https://www.ahrq.gov/cahps/about-cahps/principles/index.html>) and established an application and approval process for survey vendors who want to participate in collecting QHP enrollee experience data.

The QHP Enrollee Survey, which is based on the CAHPS® Health Plan Survey, will be used to (1) help consumers choose among competing health plans, (2) provide actionable information that the QHPs can use to improve performance, (3) provide information that regulatory and accreditation organizations can use to regulate and accredit plans, and (4)

provide a longitudinal database for consumer research. Based on the requirements for the QHP Enrollee Survey, CMS developed this survey to capture information about enrollees' experience with QHPs offered through an Exchange. CMS conducted in-depth formative research including: A comprehensive literature review, review of existing CMS survey instruments, consumer focus groups, stakeholder discussions, and input from a Technical Expert Panel (TEP). CMS performed a psychometric test and beta test in 2014 and 2015, respectively. CMS began fielding the QHP Enrollee Survey nationwide in 2016 and this request is to continue nationwide collection and administration of the statutorily-required survey in 2021 through 2023. These activities are necessary to ensure that CMS fulfills legislative mandates established by section 1311(c)(4) of the Affordable Care Act to develop an "enrollee satisfaction survey system" and provide such information on Exchange websites. *Form Number:* CMS–10488 (OMB Control Number: 0938–1221); *Frequency:* Annually; *Affected Public:* Public sector (Individuals and Households), Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 285; *Total Annual Responses:* 82,510; *Total Annual Hours:* 15,141. For policy questions regarding this collection contact Nidhi Singh Shah at 301–492–5110.

4. Type of Information Collection Request: Reinstatement without change of a previously approved collection; *Title:* Medicare Program: Procedures for Making National Coverage Decisions; *Use:* This collection is required by a notice (78 FR 48164–69) published on August 7, 2013 which delineates the process for making a national coverage determination (NCD) including information for external parties to submit a formal request for a new NCD or a reconsideration of an existing NCD. An NCD is defined in 1862(l) of the Social Security Act (the Act) as "a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under this title." This information collection will assist us in obtaining the information we require to make a national coverage determination in a timely manner and ensuring that the Medicare program continues to meet the needs of its beneficiaries. *Form Number:* CMS–R–290 (OMB control number: 0938–0776); *Frequency:* Annual; *Affected Public:* Private Sector: Business or other for-profits; *Number of Respondents:* 30; *Total Annual*

Responses: 30; *Total Annual Hours:* 1,200. (For policy questions regarding this collection contact Lori M. Ashby at 410–786–6322.)

6. Type of Information Collection Request: Revision with change of a previously approved collection; *Title:* PACE Quality Data Monitoring and Reporting; *Use:* The Programs of All-Inclusive Care for the Elderly (PACE) program is a unique model of managed care service delivery for the frail elderly, most of whom are dually-eligible for Medicare and Medicaid benefits. To be eligible to enroll in PACE, an individual must: Be 55 or older, live in the service area of a PACE organization (PO), need a nursing home-level of care (as certified by the state in which he or she lives), and be able to live safely in the community with assistance from PACE.

PACE organizations are responsible for providing all required Medicare and Medicaid covered services, and any other service that the interdisciplinary team (IDT) determines necessary to improve and maintain a participant's overall health condition (42 CFR 460.92). POs must also comply with the quality monitoring and reporting requirements outlined in §§ 460.140, 460.200(b)(1), 460.200(c) and 460.202. POs are also required to report certain unusual incidents to other Federal and State agencies consistent with applicable statutory or regulatory requirements (see 42 CFR 460.136(a)(5)). *Form Number:* CMS–R–10525 (OMB control number: 0938–1264); *Frequency:* Annual; *Affected Public:* Private Sector: Business or other for-profits; *Number of Respondents:* 131; *Total Annual Responses:* 1,143; *Total Annual Hours:* 156,414. (For policy questions regarding this collection contact Donna Williamson at 410–786–4647.)

Dated: March 18, 2020.

William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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