The Board also received comments on the implementation timeline and, in particular, how coordinating with FINRA on its own proposed changes would be beneficial. Commenters noted the importance of enough lead time prior to reporting to allow for systems to be implemented or updated as needed. The Board understands the balance between minimizing compliance burdens on depository institutions as well as the critical need to gain insight into this segment of the Treasury securities and agency-issued debt and MBS markets. As a result, the Board intends to provide appropriate lead time to permit depository institutions the necessary time to prepare before the initial reporting under this collection will be required. In addition, the Board anticipates that any modifications adopted by FINRA and incorporated in the Board's reporting requirement in the future will also provide ample lead time to prepare to comply with any proposed modifications. In response to these comments, the Board is adopting an implementation timeline for first reporting under this collection of September 1, 2022.

Board of Governors of the Federal Reserve System, October 21, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021–23432 Filed 10–27–21; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Nutrition as Prevention for Improved Cancer Outcomes

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for supplemental evidence and data submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review on *Nutrition as Prevention for Improved Cancer Outcomes,* which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before November 29, 2021.

ADDRESSES:

Email submissions: epc@ahrq.hhs.gov

Print submissions:

Mailing Address: Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E53A, Rockville, MD 20857

Shipping Address (FedEx, UPS, etc.): Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E77D, Rockville, MD 20857

FOR FURTHER INFORMATION CONTACT: Jenae Benns, Telephone: 301–427–1496 or Email: *epc@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Nutrition as Prevention for Improved Cancer Outcomes.* AHRQ is conducting this technical brief pursuant to Section 902 of the Public Health Service Act, 42 U.S.C. 299a.

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (*e.g.,* details of studies conducted). We are looking for studies that report on *Nutrition as Prevention for Improved Cancer Outcomes,* including those that describe adverse events. The entire research protocol is available online at: *https://effectivehealthcare.ahrq.gov/products/improved-cancer-outcomes/protocol.*

This is to notify the public that the EPC Program would find the following information on *Nutrition as Prevention for Improved Cancer Outcomes* helpful:

- A list of completed studies that your organization has sponsored for this indication. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.*
- *For completed studies that do not have results on ClinicalTrials.gov,* a summary, including the following elements: Study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.
- *A list of ongoing studies that your organization has sponsored for this indication.* In the list, please provide the *ClinicalTrials.gov* trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
- Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the email list at: *https://www.effectivehealthcare.ahrq.gov/email-updates.*

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

Key Questions (KQ)

KQ 1: In adults diagnosed with cancer who have or are at risk for cancer-associated malnutrition, what is the effect of nutritional interventions *prior to* cancer treatment in preventing negative treatment outcomes such as effects on dose tolerance, hospital utilizations, adverse events and survival?

a. Do the effects of nutritional interventions on preventing the negative outcomes associated with cancer treatment vary by cancer type, treatment type (chemotherapy, radiation, surgery) and stage of disease?

b. Do the effects of nutritional interventions vary across the lifespan (*e.g.,* adults aged ≥65 years vs. <65 years)?

c. KQ1c: Compared to adults without muscle wasting, do nutritional interventions prevent the negative outcomes associated with cancer

treatment in adults with muscle wasting?

d. KQ1d: Do the effects of nutritional interventions on preventing the negative outcomes associated with cancer treatment vary across special populations (*e.g.,* individuals with multiple comorbid conditions)?

KQ 2: In adults diagnosed with cancer who have or are at risk for cancer-associated malnutrition, what is the effect of nutritional interventions *during* cancer treatment in preventing negative treatment outcomes such as effects on dose tolerance, hospital utilizations, adverse events and survival?

a. Do the effects of nutritional interventions on preventing the negative outcomes associated with cancer treatment vary by cancer type, treatment type (chemotherapy, radiation, surgery) and stage of disease?

b. Do the effects of nutritional interventions vary across the lifespan (*e.g.,* adults aged ≥65 years vs. <65 years)?

c. Compared to adults without muscle wasting, do nutritional interventions prevent the negative outcomes associated with cancer treatment in adults with muscle wasting?

d. Do the effects of nutritional interventions on preventing the negative outcomes associated with cancer treatment vary across special populations (*e.g.,* individuals with multiple comorbid conditions)?

KQ 3: In adults diagnosed with cancer who have or are at risk for cancer-associated malnutrition, what is the effect of nutritional interventions *prior to* or *during* cancer treatment on associated symptoms such as fatigue, nausea and vomiting, appetite, physical and functional status (*e.g.,* frailty), and quality of life?

a. Do the effects of nutritional interventions on symptoms associated with cancer treatment vary by cancer type, treatment type (chemotherapy, radiation, surgery) and stage of disease?

b. Do the effects of nutritional interventions vary across the lifespan (*e.g.,* adults aged ≥65 years vs. <65 years)?

c. Compared to adults without muscle wasting, do nutritional interventions differentially effect symptoms associated with cancer treatment in adults with muscle wasting?

d. Do the effects of nutritional interventions on symptoms associated with cancer treatment vary across special populations (*e.g.,* individuals with multiple comorbid conditions)?

KQ 4: In adults with cancer who are overweight or obese, what is the effect of nutritional interventions intended for weight loss *prior to* or *during* cancer treatment in preventing negative treatment outcomes such as effects on dose, hospital utilizations, adverse events and survival?

Contextual Question (CQ)

CQ 1: What evidence is available on the cost-effectiveness of nutritional interventions for preventing negative outcomes associated with cancer treatment?

PICOTS (POPULATION, INTERVENTION, COMPARATOR, OUTCOME, TIMING, SETTING)

PICOTS	KQ1: pre-treatment nutritional interventions (PNIs)	KQ2: nutritional interventions during treatment (NIDTs)	KQ3: pre- or during treatment nutritional interventions (NIs) and patient-centered outcomes	KQ4: weight loss in overweight/obese adults with cancer
Population	Adults diagnosed with cancer at or after age 18 who have or are at risk for cancer-associated malnutrition. Subgroups: • Cancer and treatment characteristics (cancer type, treatment type (systemic therapy, radiation, surgery), stage of disease). • Adults ≥65y vs younger. • Muscle wasting (*e.g.,* sarcopenia, cachexia, pre-cachexia) vs. no muscle wasting. • Special populations (individuals with multiple co-morbid conditions).			Overweight (BMI 25–<30)/obese (BMI ≥30) adults ≥18y of age diagnosed with cancer.
Interventions	Nutritional interventions under the supervision of a nutrition professional (*e.g.,* dietician, nutritionist, or other licensed clinicians). • Diet or nutrition therapy (via oral or enteral (*e.g.,* nasogastric, gastrostomy, jejunostomy) feeding. ○ Special diets (*e.g.,* fasting (intermittent or short-term), calorie restriction, ketogenic, Mediterranean diet, high calorie, high protein). ○ Supplements. • Total parenteral therapy. • Nutritional counseling. • Combined nutritional interventions (*e.g.,* nutritional counseling with nutrition therapy).			Nutritional Interventions intended for weight loss (includes both PNIs and NIDTs).
Comparators	Standard of care vs PNIs or PNIs vs PNIs.	Standard of care vs NIDTs, NIDT vs NIDT or PNIs vs. NIDTs.	Standard of care vs PNIs or NIDTs, NIDTs vs. NIDTs, PNIs vs. PNIs, PNIs vs NIDTs.	Standard of care vs PNIs or NIDTs, NIDTs vs. NIDTs, PNIs vs. PNIs, PNIs vs NIDTs.
Outcomes	Intermediate Outcomes BMI, Body composition, Weight (loss, gain). Final Outcomes. Cancer treatment tolerance: treatment interruptions, reductions, or delays. Hospital utilizations: ER visits, Admissions, Length of stay. Adverse events. • Chemotherapy/radiation therapy limiting toxicity. • Post-op complication. • NI-related AEs. • Unintended harms. Survival. Nutritional status. Malnutrition (underweight, wasting, overweight).		Fatigue, nausea and vomiting, appetite, physical/functional status (*e.g.,* frailty). Quality of life	Intermediate Outcomes. BMI, Body composition, Weight (loss, gain). Final Outcomes. Cancer treatment tolerance: treatment interruptions, reductions, or delays. Hospital utilizations: ER visits. Admissions, Length of stay. Adverse events. • Chemotherapy/radiation therapy limiting toxicity. • Post-op complication. • NI-related AEs. • Unintended harms. Survival. Nutritional Status. Malnutrition (underweight, wasting, overweight).

PICOTS (POPULATION, INTERVENTION, COMPARATOR, OUTCOME, TIMING, SETTING)—Continued

PICOTS	KQ1: pre-treatment nutritional interventions (PNIs)	KQ2: nutritional interventions during treatment (NIDTs)	KQ3: pre- or during treatment nutritional interventions (NIs) and patient-centered outcomes	KQ4: weight loss in overweight/obese adults with cancer
Timing	Nutritional interventions delivered pre- cancer treatment (KQ1, KQ3, KQ4) and during cancer treatment (KQ2, KQ3, KQ4).			
Setting	Outpatient Oncology Care, Ambulatory Care, Cancer Treatment Centers, inpatient, home-based, hospice, telemedicine.			

Abbreviations: KQ = key question; BMI = body mass index; ER = emergency room; PICOTS = population, intervention, comparator, outcomes, timing, setting; RCT = randomized controlled trial; NRCT = non-randomized controlled trial.

Dated: October 22, 2021.

Marquita Cullom,

Associate Director.

[FR Doc. 2021–23456 Filed 10–27–21; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Temporary Extension and Modification of Framework for Conditional Sailing Order (CSO) for Cruise Ships Operating or Intending To Operate in U.S. Waters

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), a component of the Department of Health and Human Services (HHS), announces a temporary extension and modification of the Framework for Conditional Sailing Order (CSO).

DATES: This action is effective November 1, 2021, at 12:01 a.m. EDT upon the expiration of the current Order.

FOR FURTHER INFORMATION CONTACT: Jennifer Buigut, Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H16–4, Atlanta, GA 30329. Phone: 404–498–1600. Email: *dgmqpolicyoffice@cdc.gov.*

SUPPLEMENTARY INFORMATION: This Order temporarily extends and modifies the Framework for Conditional Sailing Order (CSO). This Order only applies to cruise ship operators in U.S. jurisdictions where foreign-flagged ships port or travel on international itineraries and state and local health departments do not routinely exercise public health jurisdiction nor maintain maritime public health programs that conduct surveillance, inspections, investigations, and management for communicable diseases with potential for significant morbidity and mortality onboard foreign-flagged ships. These specific jurisdictions are listed below in the Order.

This Order additionally applies to foreign-flagged cruise ships operating outside of U.S. waters if the cruise ship operator intends for the ship to return to operating in international, interstate, or intrastate waterways, subject to the jurisdiction of the United States during the period that this Order is in effect.

As per the Preliminary Injunction Order, entered by the U.S. District Court for the Middle District of Florida on June 18, 2021, as of July 23, 2021, the CSO and accompanying measures, such as technical instructions, are nonbinding recommendations for cruise ships arriving in, located within, or departing from a port in Florida. Accordingly, this Order shall not apply to this subset of ships while this Preliminary Injunction Order remains in effect (or in the event the Preliminary Injunction becomes permanent). However, CDC will continue to operate the CSO as a voluntary program for such ships should they choose to follow the CSO measures on a voluntary basis.

A copy of the Order is provided below and a copy of the signed order can be found at *https://www.cdc.gov/quarantine/cruise/index.html.*

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

Order Under Sections 361 & 365 of the Public Health Service Act (42 U.S.C. 264, 268) and 42 Code of Federal Regulations Part 70 (Interstate) and Part 71 (Foreign)

Temporary Extension & Modification of Framework for Conditional Sailing Order (CSO)

Executive Summary

The Centers for Disease Control and Prevention is temporarily extending the Framework for Conditional Sailing Order (CSO) issued on October 30, 2020. Since the issuance of the CSO, cruise lines, with CDC assistance, have resumed passenger operations and successfully developed and implemented health and safety protocols to manage COVID–19 that have averted overwhelming onboard medical facilities and burdening shoreside hospital resources. However, considering the continued spread of the Delta variant, emergence of other COVID–19 variants of concern, breakthrough cases among the fully vaccinated, and possible additional surges of cases and deaths, CDC has determined a temporary extension of the CSO is necessary for foreign-flagged cruise ships operating on international itineraries. After the expiration of this temporary extension, CDC intends to transition to a voluntary program, in coordination with interested cruise ship operators and other stakeholders, to assist the cruise ship industry to detect, mitigate, and control the spread of COVID–19 onboard cruise ships.

This Order shall remain in effect until the earliest of (1) the expiration of the Secretary of Health and Human Services' declaration that COVID–19 constitutes a public health emergency; (2) the CDC Director rescinds or modifies the Order based on specific public health or other considerations; or (3) January 15, 2022 at 12:01 a.m. (EST).

Previous Orders and Incorporation by Reference

The findings and other evidence relied upon in issuing the CSO are incorporated herein by reference. Any ambiguity between the October 30, 2020 Order, as further modified and extended by the current Order, shall be resolved in favor of the current Order.

Applicability

This temporary renewal and modification of the CSO shall apply only to the subset of carriers [1] described below and hereinafter referred to as ''cruise ships'':

All commercial, non-cargo,[2] foreign-flagged,[3] passenger-carrying vessels operating

[1] Carrier is defined by 42 CFR 71.1 to mean, ''a ship, aircraft, train, road vehicle, or other means of transport, including military.''

[2] Given the substantial risk of person-to-person transmission of COVID–19, as opposed to transmission via indirect contact, this Order is currently limited to passenger, non-cargo vessels.

[3] This Order modifies the CSO so that it is applicable only to foreign-flagged vessels that per 46 U.S.C. 55103 may not travel between U.S. ports