The Director, Management Analysis and Services Office, has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,
Director, Management Analysis and Services Office. Centers for Disease Control and Prevention.

[FR Doc. 2016–19787 Filed 8–18–16; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
Fees for Sanitation Inspections of Cruise Ships

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

ACTION: General notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS) announces fees for vessel sanitation inspections for Fiscal Year (FY) 2017. These inspections are conducted by HHS/CDC’s Vessel Sanitation Program (VSP). VSP helps the cruise line industry fulfill its responsibility for developing and implementing comprehensive sanitation programs to minimize the risk for acute gastroenteritis. Every vessel that has a foreign itinerary and carries 13 or more passengers is subject to twice-yearly unannounced inspections and, when necessary, reinspection.

DATES: These fees are effective October 1, 2016, through September 30, 2017.

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION:

Purpose and Background

HHS/CDC established the Vessel Sanitation Program (VSP) in the 1970s as a cooperative activity with the cruise ship industry. VSP helps the cruise ship industry prevent and control the introduction, transmission, and spread of gastrointestinal illnesses on cruise ships. VSP operates under the authority of the Public Health Service Act (Section 361 of the Public Health Service Act: 42 U.S.C. 264, “Control of Communicable Diseases”). Regulations found at 42 CFR 71.41 (Foreign Quarantine—Requirements Upon Arrival at U.S. Ports; Sanitary Inspection; General Provisions) state that carriers arriving at U.S. ports from foreign areas are subject to sanitary inspections to determine whether rodent, insect, or other vermin infestations exist, contaminated food or water, or other sanitary conditions requiring measures for the prevention of the introduction, transmission, or spread of communicable diseases are present.

The fee schedule for sanitation inspections of passenger cruise ships by VSP was first published in the Federal Register on November 24, 1987 (52 FR 45019). HHS/CDC began collecting fees on March 1, 1988. This notice announces fees that are effective for FY 2017, beginning on October 1, 2016, through September 30, 2017.

The following formula will be used to determine the fees:

\[
\text{Average cost per inspection} = \frac{\text{Total cost of VSP}}{\text{Weighted number of annual inspections}}
\]

Total cost of VSP = Total cost of operating the program, such as administration, travel, staffing, sanitation inspections, and outbreak response. Weighted number of annual inspections = Total number of ships and inspections per year accounting for vessel size, number of inspectors needed for vessel size, travel logistics to conduct inspections, and vessel location and arrivals in U.S. jurisdiction per year.

The fee schedule was originally established and published in the Federal Register on July 17, 1987 (52 FR 27064). It was most recently published in the Federal Register on August 26, 2015 (80 FR 51819). The fee schedule for FY 2017 is presented in Appendix A.

Fee

The fee schedule (Appendix A) will be effective October 1, 2016, through September 30, 2017.

Applicability

The fees will apply to all passenger cruise vessels for which inspections are conducted as part of HHS/CDC’s VSP. Inspections and reinspections involve the same procedures, require the same amount of time, and are therefore charged at the same rates.


Sandra Cashman,
Executive Secretary, Centers for Disease Control and Prevention.
Appendix A

FEE SCHEDULE FOR EACH VESSEL SIZE

<table>
<thead>
<tr>
<th>Vessel size (GRT¹)</th>
<th>Inspection fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extra Small (&lt;3,000 GRT)</td>
<td>$1,495</td>
</tr>
<tr>
<td>Small (3,001–15,000 GRT)</td>
<td>2,990</td>
</tr>
<tr>
<td>Medium (15,001–30,000 GRT)</td>
<td>5,980</td>
</tr>
<tr>
<td>Large (30,001–60,000 GRT)</td>
<td>8,970</td>
</tr>
<tr>
<td>Extra Large (60,001–120,000 GRT)</td>
<td>11,960</td>
</tr>
<tr>
<td>Mega (&gt;120,001 GRT) ......</td>
<td>17,940</td>
</tr>
</tbody>
</table>

¹ Gross register tonnage in cubic feet, as shown in Lloyd’s Register of Shipping.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1680–N]

Medicare Program; Announcement of the Advisory Panel on Clinical Diagnostic Laboratory Tests Meeting on September 12, 2016

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

ACTION: Notice.

SUMMARY: This notice announces the next meeting date of the Advisory Panel on Clinical Diagnostic Laboratory Tests (the Panel) on Monday, September 12, 2016. The purpose of the Panel is to advise the Secretary of the Department of Health and Human Services (HHS) (the Secretary) and the Acting Administrator of the Centers for Medicare & Medicaid Services (CMS) (the Acting Administrator) on issues related to clinical diagnostic laboratory tests. The Panel will address Clinical Laboratory Fee Schedule issues relevant to the June 23, 2016 final rule entitled “Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System” (81 FR 41035 through 41101), which are designated in the Panel’s charter and outlined in the agenda.

DATES: Meeting Date: The meeting of the Panel is scheduled to take place at CMS’s headquarters in Baltimore, Maryland on Monday, September 12, 2016 beginning at 9:00 a.m. and ending at 4:30 p.m., Eastern Daylight Time (e.d.t.). The times listed in this notice are Eastern Daylight Time (EDT) and are approximate times except that the meeting will not begin before the posted time.

Meeting Registration: The public may attend the meeting in-person, view via webcast, or listen via teleconference. Beginning Friday, August 19, 2016 and ending Friday, September 2, 2016 at 5:00 p.m. e.d.t., registration to attend the meeting in-person may be completed on-line at http://cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html. On this Web page, under “Related Links,” double-click the “Clinical Diagnostic Laboratory Tests FACA Panel Meeting Registration” link and enter the required information. All the following information must be submitted when registering:

- Name.
- Company name.
- Address.
- Email addresses.

Note: Participants who do not plan to attend the meeting in-person on September 12, 2016 should not register. No registration is required for participants who plan to view the meeting via webcast or listen via teleconference.

Presenter Registration and Submission of Presentations and Comments: We are interested in submitted comments or in-person presentations at the meeting concerning the issues described in the SUPPLEMENTARY INFORMATION section of this notice and clarified in the agenda to be published approximately 2 weeks before the meeting. The comments and presentations should not address issues not before the Panel. The deadline to register to be a presenter and to submit written presentations for the meeting is 5:00 p.m. e.d.t., Friday, September 2, 2016. Presenters may register by email by contacting the person listed in the FOR FURTHER INFORMATION CONTACT section of this notice. Presentations should be sent via email to the same person’s email address.

ADDRESSES: Meeting Location and Webcast: The meeting will be held in the Auditorium, CMS Central Office, 7500 Security Boulevard, Woodlawn, Maryland 21244–1850. Alternately, the public may either view the meeting via a webcast at http://cms.gov/live.


FOR FURTHER INFORMATION CONTACT: Glenn C. McGuirk, Designated Federal Official (DFO), Center for Medicare, Division of Ambulatory Services, CMS, 7500 Security Boulevard, Mail Stop C4–01–26, Baltimore, MD 21244, 410–786–5723, email CDLTPanel@cms.hhs.gov or Glenn.McGuirk@cms.hhs.gov. Press inquiries are handled through the CMS Press Office at (202) 690–6145.

SUPPLEMENTARY INFORMATION:

I. Background


Section 1834A(f)(1) of the Act directs the Secretary of the Department of Health and Human Services (Secretary) to consult with an expert outside advisory panel, established by the Secretary, composed of an appropriate selection of individuals with expertise in issues related to clinical diagnostic laboratory tests. Such individuals may include molecular pathologists, clinical laboratory researchers, and individuals with expertise in laboratory science or health economics.

The Panel will provide input and recommendations to the Secretary and the Acting Administrator of the Centers for Medicare & Medicaid Services (CMS), on the following:

- The establishment of payment rates under section 1834A of the Act for new clinical diagnostic laboratory tests, including whether to use crosswalking or gapfilling processes to determine payment for a specific new test;
- The factors used in determining coverage and payment processes for new clinical diagnostic laboratory tests; and
- Other aspects of the new payment system, to be based on private payor rates, under section 1834A of the Act.

A notice announcing the establishment of the Panel and soliciting nominations for members was published in the October 27, 2014 Federal Register (79 FR 63919 through 63920). In the August 7, 2015 Federal Register (80 FR 47491), we announced membership appointments to the Panel along with the first public meeting date for the Panel, which was held on August 26, 2015. Subsequent public meetings for the Panel were held on October 19, 2015 (80 FR 59782) and July 18, 2016 (81 FR 35772). Recommendations from Panel meetings are posted on the CMS Web site listed in the ADDRESSES section of this notice.

For more information on the Advisory Panel on Clinical Diagnostic Laboratory Tests, visit our Web site at http://CMS.GOV/Live.