

Authorized contractors shall submit requests for IFMS vehicles and related services in writing to the appropriate GSA point of contact in accordance with the FAR. Contractors' requests must include: (1) Two copies of the agency authorization; (2) The number of vehicles and related services required and period of use; (3) A list of employees who are authorized to request the vehicles or related services; (4) A listing of equipment authorized to be serviced; and (5) Billing instructions and address.

### C. Annual Burden

*Respondents:* 132.

*Total Annual Responses:* 132.

*Total Burden Hours:* 132.

*Obtaining Copies:* Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW, Washington, DC 20405, telephone 202-501-4755. Please cite OMB Control No. 9000-0032, Contractor Use of Interagency Fleet Management System Vehicles, in all correspondence.

Dated: October 2, 2019.

**Janet Fry,**

*Director, Federal Acquisition Policy Division,  
Office of Governmentwide Acquisition Policy,  
Office of Acquisition Policy, Office of  
Governmentwide Policy.*

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**BILLING CODE 6820-EP-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### National Inventory for Poliovirus Containment: Minimizing Risk of Poliovirus Release From Laboratories in the United States; Availability

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

**ACTION:** Notice.

**SUMMARY:** The United States National Authority for Containment of Poliovirus (NAC), Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS), announces the availability of the National Inventory for Poliovirus Containment survey. This survey is designed to collect relevant laboratory inventory data to ensure facilities throughout the United States are in compliance with requirements established in the World Health Organization (WHO) Global Action Plan (GAPIII), as adapted for the

WHO Region of the Americas. Per GAPIII, each country is required to complete a national inventory of poliovirus-containing materials, including poliovirus potentially infectious materials (PIM).

**DATES:** The deadline for completion of the survey is December 31, 2019.

**FOR FURTHER INFORMATION CONTACT:** Lia Haynes Smith, Director, National Authority for Containment of Poliovirus, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21-6, Atlanta, GA 30329. Telephone: (404)718-5160.

**SUPPLEMENTARY INFORMATION:** The survey should be completed by laboratories, storage sites, or other facilities that test, extract, handle, or store biological samples from humans, experimentally infected animals, sewage, or environmental waters. The survey questions are intended to identify facilities that possess any materials that may contain poliovirus. The questions seek to distinguish between potentially infectious materials (PIM) containing wild poliovirus (WPV), circulating vaccine-derived poliovirus (cVDPV), and oral poliovirus vaccine (OPV). PIM includes historical domestic and international specimens, human respiratory secretions, fecal specimens and environmental samples collected for non-polio related work in a time and place where wild poliovirus (WPV) or vaccine-derived poliovirus (cVDPV) was circulating or where oral polio vaccine (OPV) was in use. A table of country-specific poliovirus data can be found at <http://polioeradication.org/wp-content/uploads/2018/11/PIM-Annex-2-16-Nov-18.pdf>. Additionally, PIM cultured in some common cell lines in order to isolate other viruses of interest may have unintentionally amplified poliovirus, so respiratory or enteric viral isolates obtained from PIM specimens using these cell lines are also considered PIM. With the release of the WHO PIM guidance in April 2018, nucleic acid extracted using a validated method and specimens that potentially contain only OPV (OPV PIM), are no longer subject to containment under WHO GAP III. However, they are still considered part of the U.S. inventory and should be reported.

For the purpose of this survey, PIM should be identified based on where and when the specimens were collected, not based on any test results.

If a facility intends to destroy any of the potentially infectious poliovirus material or infectious material it possesses, it must submit material destruction attestation to the NAC. The NAC will send this attestation form to

the facility once the completed survey is received.

Although the U.S. no longer immunizes with OPV, poliovirus materials are still present within a limited number of U.S. facilities for public health and virologic research, as well as diagnostic and manufacturing-related purposes. In these essential facilities [poliovirus-essential facilities; PEFs], poliovirus materials will continue to be retained, post-eradication, to serve critical national and international functions. It is crucial that poliovirus materials are appropriately contained under strict biosafety and biosecurity handling and storage conditions to ensure that the virus is not released into the environment, either accidentally or intentionally, to cause outbreaks of the disease in susceptible populations. The risk from a poliovirus reintroduction can be minimized, in part, by ensuring that facilities retaining poliovirus are located in areas with high levels of vaccination coverage. The data collected from this survey will be used to identify facilities with poliovirus materials, to inform poliovirus immunization activities at PEFs including the potential need to immunize particular facility staff, and to identify vaccination coverage estimates for communities surrounding these facilities.

### Survey Overview

An overview of the survey questions can be found at [https://www.cdc.gov/cpr/polioviruscontainment/00\\_docs/SurveyGuidance.pdf](https://www.cdc.gov/cpr/polioviruscontainment/00_docs/SurveyGuidance.pdf). This overview document is provided to help facilities prepare their survey responses and is not intended to be completed as a paper-based format. The survey must be completed online.

Access to the survey, including appendices and other references, can be found at <https://www.cdc.gov/cpr/polioviruscontainment/NIPC.htm>. The time needed to complete the online survey will vary depending on the complexity of a facility and the availability of needed information.

### Paperwork Reduction Act

CDC has determined that the information collection activities conducted under this project are exempt from the requirements of the Paperwork Reduction Act (PRA) as they fall under the activities authorized under the National Childhood Vaccine Injury Act (NCVIA) at section 2102(a)(6)-(a)(7) of the Public Health Service Act (42 U.S.C. 300aa-2(a)(6)-(a)(7)).

Dated: October 2, 2019.

**Sandra Cashman,**

*Executive Secretary, Centers for Disease Control and Prevention.*

[FR Doc. 2019-21864 Filed 10-7-19; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-1722-N]

#### Medicare Program; Town Hall Meeting on the FY 2021 Applications for New Medical Services and Technologies Add-On Payments

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

**ACTION:** Notice of meeting.

**SUMMARY:** This notice announces a Town Hall meeting in accordance with section 1886(d)(5)(K)(viii) of the Social Security Act (the Act) to discuss fiscal year (FY) 2021 applications for add-on payments for new medical services and technologies under the hospital inpatient prospective payment system (IPPS). Interested parties are invited to this meeting to present their comments, recommendations, and data regarding whether the FY 2021 new medical services and technologies applications meet the substantial clinical improvement criterion.

**DATES:** *Meeting Date:* The Town Hall Meeting announced in this notice will be held on Monday, December 16, 2019 and Tuesday December 17, 2019 (the number of new technology applications submitted will determine if a second day for the meeting is necessary; see the **SUPPLEMENTARY INFORMATION** section for details regarding the second day of the meeting and the posting of the preliminary meeting agenda). The Town Hall Meeting will begin each day at 9:00 a.m. Eastern Standard Time (e.s.t.) and check-in will begin at 8:30 a.m. e.s.t.

*Deadline for Registration for Participants (not Presenting) at the Town Hall Meeting:* The deadline to register to attend the Town Hall Meeting is 5:00 p.m. e.s.t. on Monday, December 9, 2019.

*Deadline for Requesting Special Accommodations:* The deadline to submit requests for special accommodations is 5 p.m. e.s.t. on Monday, November 25, 2019.

*Deadline for Registration of Presenters at the Town Hall Meeting:* The deadline to register to present at the Town Hall Meeting is 5 p.m. e.s.t. on Monday, November 18, 2019.

*Deadline for Submission of Agenda Item(s) or Written Comments for the Town Hall Meeting:* Written comments and agenda items for discussion at the Town Hall Meeting, including agenda items by presenters, must be received by 5 p.m. e.s.t. on Monday, November 25, 2019.

*Deadline for Submission of Written Comments after the Town Hall Meeting for consideration in the FY 2021 IPPS proposed rule:* Individuals may submit written comments after the Town Hall Meeting, as specified in the **ADDRESSES** section of this notice, on whether the service or technology represents a substantial clinical improvement. These comments must be received by 5:00 p.m. e.s.t. on Friday, January 3, 2020, for consideration in the FY 2021 IPPS proposed rule.

**ADDRESSES:** *Meeting Location:* The Town Hall Meeting will be held in the main Auditorium in the central building of the Centers for Medicare & Medicaid Services located at 7500 Security Boulevard, Baltimore, MD 21244-1850.

In addition, we are providing two alternatives to attending the meeting in person—(1) there will be an open toll-free phone line to call into the Town Hall Meeting; or (2) participants may view and participate in the Town Hall Meeting via live stream technology or webinar. These options are discussed in section II.B. of this notice.

*Registration and Special Accommodations:* Individuals wishing to participate in the meeting must register by following the on-line registration instructions located in section III of this notice or by contacting staff listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Individuals who need special accommodations should contact staff listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

*Submission of Agenda Item(s) or Written Comments for the Town Hall Meeting:* Each presenter must submit an agenda item(s) regarding whether a FY 2021 application meets the substantial clinical improvement criterion. Agenda items, written comments, questions or other statements must not exceed three single-spaced typed pages and may be sent via email to [newtech@cms.hhs.gov](mailto:newtech@cms.hhs.gov).

**FOR FURTHER INFORMATION CONTACT:**

Michelle Joshua, (410) 786-6050, [michelle.joshua@cms.hhs.gov](mailto:michelle.joshua@cms.hhs.gov); or Michael Treitel, (410) 786-4552, [michael.treitel@cms.hhs.gov](mailto:michael.treitel@cms.hhs.gov).

Alternatively, you may forward your requests via email to [newtech@cms.hhs.gov](mailto:newtech@cms.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

#### I. Background on the Add-On Payments for New Medical Services and Technologies Under the IPPS

Sections 1886(d)(5)(K) and (L) of the Social Security Act (the Act) require the Secretary to establish a process of identifying and ensuring adequate payments to acute care hospitals for new medical services and technologies under Medicare. Effective for discharges beginning on or after October 1, 2001, section 1886(d)(5)(K)(i) of the Act requires the Secretary to establish (after notice and opportunity for public comment) a mechanism to recognize the costs of new services and technologies under the hospital inpatient prospective payment system (IPPS). In addition, section 1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will be considered “new” if it meets criteria established by the Secretary (after notice and opportunity for public comment). (See the fiscal year (FY) 2002 IPPS proposed rule (66 FR 22693, May 4, 2001) and final rule (66 FR 46912, September 7, 2001) for a more detailed discussion.) As finalized in the FY 2020 IPPS/LTCH PPS final rule, technologies which are eligible for the alternative new technology pathway for transformative new devices or the alternative new technology pathway for Qualified Infectious Disease Products do not need to meet the requirement under 42 CFR 412.87(b)(1) that the technology represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. These medical devices or products will also be considered new and not substantially similar to an existing technology for purposes of new technology add-on payment under the IPPS. (See the FY 2020 IPPS/LTCH PPS final rule (84 FR 42292 through 42297) for additional information.)

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42289 through 42292), we codified in our regulations at § 412.87 the following aspects of how we evaluate substantial clinical improvement for purposes of new technology add-on payments under the IPPS in order to determine if a new technology meets the substantial clinical improvement requirement:

- The totality of the circumstances is considered when making a determination that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries.
- A determination that a new medical service or technology represents an