

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-5508-N]

Medicare Program; Comprehensive Primary Care Initiative

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

ACTION: Notice.

SUMMARY: This notice announces a solicitation for health care payer organizations to participate in the Comprehensive Primary Care initiative (CPC), a multipayer model designed to improve primary care.

DATES: *Letter of Intent Submission Deadlines:* Interested organizations must submit a nonbinding letter of intent (LOI), which includes an Excel document identifying preliminary markets of interest by November 15, 2011 using the LOI template provided on the Innovation Center Web site at <http://www.innovation.cms.gov/>.

Application Submission Deadline: Applications must be received through an online portal, on or before 5 p.m., Eastern Standard Time (E.S.T) on January 17, 2012. We reserve the right to request additional information from applicants in order to assess their applications.

ADDRESSES: Letters of Intent should be submitted electronically in PDF format via encrypted e-mail to the following e-mail address by the applicable date specified in the **DATES** section of this notice: CPCi@cms.hhs.gov. Letters of Intent will only be accepted via e-mail. Applications will only be accepted via the online application portal.

FOR FURTHER INFORMATION CONTACT: CPCi@cms.hhs.gov for questions regarding the aspects of the Comprehensive Primary Care initiative or the application process.

SUPPLEMENTARY INFORMATION:

I. Background

The Centers for Medicare & Medicaid Services (CMS) are committed to the three-part aim of better health, better health care, and lower per-capita costs for Medicare, Medicaid and Children's Health Insurance Program (CHIP) beneficiaries. One potential mechanism for achieving this goal is to support practice redesign in primary care through payment reform.

The Center for Medicare & Medicaid Innovation (Innovation Center) is seeking to strengthen free-standing primary care capacity by testing a model

of comprehensive, accountable primary care supported by multiple payers. We are seeking to collaborate with other payers in select markets and with approximately 75 primary care practices in each market over the course of this 4-year initiative. This solicitation is directed to public and private health care payers who will respond individually to the Innovation Center. Once payers and markets have been selected, primary care practices will be recruited and selected in those markets.

II. Provisions of the Notice

Consistent with its authority under section 1115A of the Social Security Act (the Act) as added by section 3021 of the Affordable Care Act, to test innovative payment and service delivery models that reduce spending under Medicare, Medicaid or CHIP, while preserving or enhancing the quality of care, the Innovation Center aims to achieve the following goals through the implementation of the Comprehensive Primary Care (CPC) initiative:

- To collaborate with other payers on aligned strategies to support the delivery of comprehensive primary care services provided by practices participating in the initiative (as described in Section D of the solicitation).

- To test whether a set of comprehensive primary care functions, coupled with payment reform, use of data to guide improvement, and meaningful use of health information technology can achieve the three-part aim of better care, improved health and reduced costs that could ultimately be adopted by Medicare and Medicaid programs.

We will pay a per-beneficiary-per-month care management payment to each participating primary care practices for comprehensive primary care services that the practice provides to its Medicare fee-for-service beneficiaries. We will offer an opportunity for participating practices to share in savings in years 2 through 4 of the program if the market in which the practice participates experiences reductions in its total health system costs (as described in Section F of the solicitation). Each payer applying for this initiative will propose a strategy that is aligned with the Innovation Center's approach to supporting comprehensive primary care. Learning systems will support participating practices throughout the initiative. Payer selection criteria are described in section II of the Solicitation.

To the extent that States apply, the Innovation Center will also pay a per-

beneficiary-per-month care management payment to primary care on behalf of Medicaid fee-for-service beneficiaries; shared savings will not be a part of the payment methodology for Medicaid fee-for-service.

III. Collection of Information Requirements

Section 1115A(d)(3) of the Act specifies that the requirements of the Paperwork Reduction Act of 1995 do not apply with respect to the testing and evaluation of payment and service delivery models or the expansion of these models under section 1115A of the Act.

Authority: Section 1115A of the Social Security Act.

Dated: September 27, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0689]

Draft Guidance for Industry and Food and Drug Administration Staff; De Novo Classification Process (Evaluation of Automatic Class III Designation); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "*De Novo Classification Process (Evaluation of Automatic Class III Designation)*." The purpose of this document is to provide guidance to FDA staff and industry on the process for the submission and review of petitions submitted under the Federal Food, Drug, and Cosmetic Act (FD&C Act), also known as the de novo classification process. FDA is issuing this draft guidance to provide updated recommendations for efficient interaction with FDA, including what information to submit, when seeking a path to market for a novel device via the de novo process. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the