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 reductions in its total health system costs (a 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-forservice 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.

[FR Doc. 2011–25356 Filed 9–28–11; 11:15 am]

BILLING CODE 4120–01–P

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

final version of the guidance, submit either electronic or written comments on the draft guidance by December 2, 2011. Submit either electronic or written comments concerning proposed collection of information by December 2, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''*De Novo* Classification Process (Evaluation of Automatic Class III Designation)'' to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002 or to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Melissa Burns, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1646, Silver Spring, MD 20993–0002, 301–796–5616; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301–827–6210.

I. Background

A medical device that is of a new type that FDA has not yet classified based on risk, and therefore cannot be found to be substantially equivalent to a legally marketed predicate device, may remain in class III even if the risks it presents are relatively low. This is the scenario targeted by Congress when it enacted section 513(f)(2) of the FD&C Act (21 U.S.C. 360c(f)(2)) as part of the Food and Drug Administration Modernization Act of 1997 (FDAMA). The process created by this provision is referred to in FDAMA as the Evaluation of Automatic Class III Designation (e.g., the de novo process). Congress included this section to limit unnecessary expenditure of FDA and industry resources that could occur if lower risk devices were subject to premarket approval under section 515 of the FD&C Act (21 U.S.C. 360e).

FDA issued a guidance document to explain the procedures involved with the de novo program, which has been in place since 1998. Over the past 13 years, even though a number of new medical devices have been evaluated by FDA under the de novo process, FDA believes that the program has been under-utilized, and has evaluated what improvements could be made to enhance the utility and productivity of the program. FDA evaluated its extensive experience gained with respect to the evidence necessary to conduct comprehensive reviews of de novo applications. Accordingly, FDA is issuing this draft guidance to provide updated recommendations designed to foster efficient interaction with FDA, including what information to submit, when seeking a path to market via the de novo process. This guidance describes a mechanism to provide greater clarity about the suitability of a device for de novo review, and timely input on the type of data necessary to support de novo classification of an eligible device.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the de novo classification process. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at http://www.regulations.gov or from CBER at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm.* To receive ''*De Novo* Classification Process (Evaluation of Automatic Class III Designation),'' from CDRH you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1769 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

Under the PRA (44 U.S.C. 3501–3502), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''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 (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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

This draft guidance describes how FDA's Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER) intend to implement this provision of the law. When final, this document will supersede ''New Section 513(f)(2)—Evaluation of Automatic Class III Designation, Guidance for Industry and CDRH Staff'' dated February 19, 1998.

The proposed collections of information are necessary to satisfy the previously mentioned statutory requirements for implementing this voluntary submission program.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Submission of information for de novo petition program	Number of respondents	Number of responses per respondent per year	Total annual responses	Average burden per respondent (in hours)	Total hours
CDRH	25	1	25	100	2,500
CBER	1	1	1	100	100
Total					2,600

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Respondents are medical device manufacturers seeking to market medical device products that have been classified into class III under section 513(f)(2) of the FD&C Act. Based on FDA's experience with the de novo petition program, FDA expects the program to continue to be utilized as a viable program in the future. It is expected that the number of petitions will increase over its current rate and reach a steady rate of approximately 26 submissions per year

FDA estimates from past experience with the de novo petition program that the complete process involved with the program takes approximately 100 hours. This average is based upon estimates by FDA administrative and technical staff who are familiar with the requirements for submission of a de novo petition (and related materials), have consulted and advised manufacturers on these requirements, and have reviewed the documentation submitted.

Therefore, the total reporting burden hours is estimated to be 2,600 hours.

TABLE 2

Number of respondents	Total burden hours annualized	Hourly wage rate	Total cost annualized
26	100	$150	$390,000

The average to industry per hour for this type of work is $150, resulting in a cost of $15,000 per respondent. The estimated submission cost of $15,000 multiplied by 26 submissions per year equals $390,000, which is the aggregated industry reporting cost annualized.

This draft guidance also refers to currently approved information collections found in FDA regulations. The collections of information in 21 CFR part 807, subpart E, are approved under OMB control number 0910–0120.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 27, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2011–25367 Filed 9–30–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review: Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office at (301) 443–1129. The following request has been submitted to OMB for review under the Paperwork Reduction Act of 1995:

Proposed Project: ADAP Data Report—[New]

HRSA's AIDS Drug Assistance Program (ADAP) is funded through the Ryan White HIV/AIDS Program, Part B, of Title XXVI of the Public Health Service Act, which provides grants to states and territories. Each of the 50 states, the District of Columbia, Puerto Rico, and several territories receive ADAP grants. The ADAP provides medications for the treatment of HIV/AIDS. Program funds may also be used to purchase health insurance for eligible clients or for services that enhance access, adherence, and monitoring of drug treatments.

The Ryan White HIV/AIDS Program specifies HRSA's responsibilities in the administration of grant funds, the allocation of funds, the evaluation of programs for the population served, and the improvement of quality of care. Accurate records of the grantees receiving Ryan White HIV/AIDS Program funding, the services provided, and the clients served, continue to be critical issues for the implementation of the legislation and are necessary for HRSA to fulfill its responsibilities.

The ADAP Data Report (ADR) provides data on the characteristics of ADAP grantees and the clients being served with program funds. The ADR is