1.9 percent (which equals the 2.7 percent estimated RPL market basket increase factor for FY 2013 reduced by 0.1 percentage points, and further reduced by a 0.7 percent productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act).

We considered maintaining the existing CMG relative weights and average length of stay values for FY 2013. However, in light of recently available data and our desire to ensure that the CMG relative weights and average length of stay values are as reflective as possible of recent changes in IRF utilization and case mix, we believe that it is appropriate to update the CMG relative weights and average length of stay values at this time to ensure that IRF PPS payments continue to reflect as accurately as possible the current costs of care in IRFs.

We considered maintaining the existing outlier threshold amount for FY 2013. However, analysis of updated FY 2011 data indicates that estimated outlier payments would be lower than 3 percent of total estimated payments for FY 2012, by approximately 0.2 percent, unless we updated the outlier threshold amount. Consequently, we are adjusting the outlier threshold amount in this notice to reflect a 0.2 percent increase thereby setting the total outlier payments equal to 3 percent, instead of 2.8 percent, of aggregate estimated payments in FY 2013.

*E. Accounting Statement*

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/sites/default/files/omb/assets/omb/circulars/a004/a-4.pdf*), in Table 8 below, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this notice. This table provides our best estimate of the increase in Medicare payments under the IRF PPS as a result of the updates presented in this notice based on the data for 1,139 IRFs in our database.

TABLE 8—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM THE 2012 IRF PPS FISCAL YEAR TO THE 2013 IRF PPS FISCAL YEAR

| Category | Transfers |
|---|---|
| Annualized Monetized Transfers | $140 million. |
| From Whom to Whom? | Federal Government to IRF Medicare Providers. |

*F. Conclusion*

Overall, the estimated payments per discharge for IRFs in FY 2013 are projected to increase by 2.1 percent, compared with the estimated payments in FY 2012, as reflected in column 8 of Table 7. IRF payments per discharge are estimated to increase 2.0 percent in urban areas and 2.2 percent in rural areas, compared with estimated FY 2012 payments. Payments per discharge to rehabilitation units are estimated to increase 2.2 percent in urban areas and 2.3 percent in rural areas. Payments per discharge to freestanding rehabilitation hospitals are estimated to increase 1.9 percent in urban areas and 1.7 percent in rural areas.

Overall, no IRFs are estimated to experience a net decrease in payments as a result of the updates in this notice. The largest payment increase is estimated to be a 3.2 percent increase for rural IRFs located in the New England region. This is due to the larger than average positive effect of the FY 2013 CBSA wage index and labor-related share updates for rural IRFs in this region.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

**Authority:** (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program).

Dated: May 10, 2012.

**Marilyn Tavenner,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

Approved: July 16, 2012.

**Kathleen Sebelius,**

*Secretary.*

[FR Doc. 2012–18433 Filed 7–25–12; 4:15 pm]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2012–D–0049]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by August 29, 2012.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–NEW and title ''Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act.'' Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

### Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act—(OMB Control Number 0910–NEW)

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Public Law 111–31) into law. This law amends the Federal Food, Drug, and Cosmetic Act (FD&C Act) and grants FDA authority to

regulate the manufacture, marketing, and distribution of tobacco products to protect public health generally and to reduce tobacco use by minors. Section 904(a)(3) of the FD&C Act (21 U.S.C. 387d(a)(3)) requires each tobacco product manufacturer or importer, or an agent, to begin reporting to FDA no later than June 22, 2012, ''all constituents, including smoke constituents, identified by [FDA] as harmful or potentially harmful to health in each tobacco product, and as applicable in the smoke of each tobacco product.'' Reports must be by the brand and by quantity in each brand and subbrand. Section 904(c)(1) of the FD&C Act states that manufacturers of tobacco products not on the market as of June 22, 2009, must also provide information reportable under section 904(a)(3) at least 90 days prior to introducing the product into interstate commerce.

FDA has taken several steps to identify harmful and potentially harmful constituents (HPHCs) to be reported under sections 904(a)(3) and (c)(1) of the FD&C Act, including issuing a final guidance discussing FDA's current thinking on the meaning of ''harmful and potentially harmful constituent'' in the context of implementing the HPHC list requirement (76 FR 5387, January 31, 2011). The guidance is available on the Internet at *http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm241339.htm.* In addition, in the **Federal Register** of April 3, 2012 (77 FR 20034), FDA published a notice (the HPHC list notice) announcing the established list of HPHCs as required by section 904(e) of the FD&C Act and describing the criteria we used in identifying the HPHCs for the established list. Previously, FDA sought comment on both the criteria that would be used to identify HPHCs for the established list and a list of chemicals and chemical compounds that met the proposed criteria.

In the **Federal Register** of April 3, 2012 (77 FR 20030), FDA announced the availability of a draft guidance entitled ''Guidance for Industry: Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under Section 904(a)(3) of the Federal Food, Drug, and Cosmetic Act'' (904(a)(3) draft guidance) discussing the information to be reported on HPHCs in tobacco products and tobacco smoke under sections 904(a)(3) and (c)(1) of the FD&C Act. The 904(a)(3) draft guidance discusses, among other things: The statutory requirement for testing and reporting quantities of HPHCs, who tests and reports quantities of HPHCs to FDA, what HPHCs will be the focus of FDA enforcement at this time, when reports are submitted to FDA, what information is reported to FDA, and how the reports should be submitted to FDA. The 904(a)(3) draft guidance notifies manufacturers and importers that, at this time, while industry is developing laboratory capacity to comply with section 904(a)(3) of the FD&C Act, FDA does not intend to enforce the statutory requirement to submit quantities of all constituents identified by FDA as HPHCs by June 22, 2012, where manufacturers or importers complete testing and reporting for an abbreviated list of HPHCs as set forth in the 904(a)(3) draft guidance. In particular, at this time, for products that were first marketed before June 22, 2012, FDA does not intend to enforce the section 904(a)(3) requirement to test and report quantities of all HPHCs on FDA's established list where: (1) A manufacturer or importer (or agents thereof), other than a small tobacco product manufacturer, submits quantities of the HPHCs on an abbreviated list described in the guidance for all of its products, by brand and subbrand, no later than September 22, 2012 or (2) a small tobacco product manufacturer (or agents thereof) submits quantities of HPHCS on the abbreviated list for all of its products, by brand and subbrand, by December 22, 2012. In addition, for products first marketed on or after June 22, 2012, the 904(a)(3) draft guidance explains that FDA does not intend, at this time, to enforce the requirement in section 904(c)(1) of the FD&C Act to test and report quantities of all HPHCs on FDA's established list for products not previously on the market if a manufacturer or importer reports quantities for the abbreviated list of HPHCs at least 90 days prior to marketing the product in the United States. The 904(a)(3) draft guidance explains that, at this time, FDA intends to enforce the HPHC reporting requirements with respect to manufacturers of finished tobacco products for consumer use—cigarettes, smokeless tobacco, and roll-your-own tobacco—and not with respect to manufacturers and importers of other products, such as components sold to manufacturers or consumers for incorporation into finished products.

The purpose of the proposed information collection is for FDA to collect statutorily mandated information regarding HPHCs in tobacco products and tobacco smoke, by quantity in each brand and subbrand. The 904(a)(3) draft guidance provides an abbreviated list of HPHCs on which FDA intends to focus enforcement at this time for each of the following: Cigarette smoke, smokeless tobacco products, and roll-your-own tobacco and cigarette filler.

To facilitate the submission of HPHC information, FDA has developed Form 3787 in both paper and electronic formats. Manufacturers or importers, or an agent, may submit information either electronically or in paper format. The FDA eSubmitter tool provides electronic forms to streamline the data entry and submission process for reporting HPHCs. Users of eSubmitter may also populate an Excel file and import data into eSubmitter. FDA also provides paper forms for the submission of section 904(a)(3) reports. FDA placed draft copies of the paper forms and screen shots of the electronic form and spreadsheet in this docket. Whether respondents decide to submit reports electronically or on paper, each form provides instructions for filling out and submitting HPHC information to FDA. The forms contain fields for company information, product information, and HPHC information (including the specific HPHCs identified in the 904(a)(3) draft guidance).

The **Federal Register** notice announcing the availability of the 904(a)(3) draft guidance included a 60-day notice requesting public comment on the proposed collection of information. FDA received 16 comments that were PRA-related, including but not limited to the following issues:

- Suggestions to enhance the quality, utility, and clarity of the information to be collected (i.e., comments specific to FDA's eSubmitter tool and paper forms);
- Cost associated with the collection of information to comply with section 904(a)(3) of the FD&C Act, particularly for small tobacco product manufacturers; and
- Use of the proposed information collection, especially because specific test methods are not prescribed to determine HPHC quantities.

Section 904(a)(3) of the FD&C Act requires HPHC testing and reporting. We have stated that we intend to exercise enforcement discretion for manufacturers who test for 20 rather than 93 HPHCs at this time. In addition, we have recognized that small tobacco product manufacturers are likely to rely on contract testing laboratories and intend to exercise enforcement discretion for those who submit quantities of HPHCs 6 months after the statutory deadline (i.e., December 22, 2012), and 3 months after submissions by other tobacco product manufacturers. Our abbreviated list of HPHCs, along with the timeframes described in the

draft guidance, represent a reasonable approach to implementing section 904(a)(3) of the FD&C Act.

Based on comments received, FDA has revised the instructions for FDA Form 3787 to explain that if the HPHC quantity is below the limit of detection or limit of quantitation, zero should be entered in the space identified for form. We have also made minor cosmetic changes to clarify instructions and to allow accurate data entry. FDA has not revised the burden estimate for this collection of information.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| Information collected | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Part 1—Section 904(a)(3) of the FD&C Act (Annualized estimate of one-time reporting) [2] | | | | | |
| 1. Reporting of Manufacturer/Importer Company and Product Information by Completing Submission Forms | | | | | |
| Cigarette | 120 | 10.10 | 1,212 | 2 | 2,424 |
| Roll-Your-Own | 46 | 3.22 | 148 | 2 | 296 |
| Smokeless | 200 | 1.44 | 288 | 2 | 576 |
| Total | | | | | 3,296 |
| 2. Testing of HPHC Quantities in Products | | | | | |
| Cigarette Filler | 120 | 10.1 | 1,212 | 9.42 | 11,417 |
| Roll-Your-Own | 46 | 3.22 | 148 | 9.42 | 1,394 |
| Smokeless | 200 | 1.44 | 288 | 12.06 | 3,473 |
| Total | | | | | 16,284 |
| 3. Testing of HPHC Quantities in Mainstream Smoke | | | | | |
| Cigarette: International Organization for Standardization (ISO) Regimen | 120 | 10.1 | 1,212 | 23.64 | 28,652 |
| Cigarette: Health Canada Regimen | 120 | 10.1 | 1,212 | 23.64 | 28,652 |
| Total | | | | | 57,304 |
| Total Section 904(a)(3) Annualized One-Time Burden | | | | | 76,884 |
| Part 2—Reporting of Section 904(c)(1) New Products (15% of One-Time Burden Totals) [3] | | | | | |
| 1. Reporting of Manufacturer/Importer Company and Product Information by Completing Submission Forms | | | | | |
| Cigarette | 18 | 10.10 | 182 | 2 | 364 |
| Roll-Your-Own | 7 | 3.22 | 23 | 2 | 46 |
| Smokeless | 30 | 1.44 | 43 | 2 | 86 |
| Total | | | | | 496 |
| 2. Reporting of HPHC Quantities in Products | | | | | |
| Cigarette Filler | 18 | 10.1 | 182 | 9.42 | 1,714 |
| Roll-Your-Own | 7 | 3.22 | 23 | 9.42 | 217 |
| Smokeless | 30 | 1.44 | 43 | 12.06 | 519 |
| Total | | | | | 2,450 |
| 3. Reporting of HPHC Quantities in Mainstream Smoke | | | | | |
| Cigarette: ISO Regimen | 18 | 10.1 | 182 | 23.64 | 4,302 |
| Cigarette: Health Canada Regimen | 18 | 10.1 | 182 | 23.64 | 4,302 |
| Total | | | | | 8,604 |
| Total Section 904(c)(1) Burden | | | | | 11,550 |
| Total Reporting Burden Hours | | | | | 88,434 |

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

[2] One-time actual first year burden hours have been annualized over the 3-year OMB period of approval to avoid over counting the burden each year.

[3] Annual new product reporting under section 904(c)(1) of the FD&C Act is estimated to be 15 percent of the annualized one-time burden.

FDA estimates the one-time reporting burden for this guidance would be 230,652 hours during the first year for section 904(a)(3) of the FD&C Act reporting plus ongoing annual burden of 11,550 hours for section 904(c)(1) reporting. The burden estimate for this collection of information includes the time it will take to read the guidance document, test the products, and prepare the HPHC report.

To avoid overcounting the one-time reporting burden, FDA has annualized the one-time burden over the 3-year expected OMB period of approval. The annualized one-time burden of 76,884 hours is located in part one of table 1 of this document, and includes burden for collections of information gathered under section 904(a)(3) of the FD&C Act. The total annual burden for this collection of information is estimated to be 88,434 hours, which is the annualized one-time burden estimate for section 904(a)(3) of the FD&C Act associated with the submission of HPHC reports and the annual burden estimate for section 904(c)(1). Table 1 of this document estimates 366 respondents will submit HPHC reports on a one-time basis. Table 1 of this document addresses the time required for manufacturers and importers to report their company information. We estimate that the burden is no more than 2 hours per response to report company and product information, regardless of whether the paper or electronic form (Form FDA 3787) is used. This estimate is not dependent on product type, so the estimated burden is the same for cigarettes, roll-your-own tobacco, and smokeless tobacco products. We also estimate that 3,636 cigarette subbrands, 445 roll-your-own tobacco subbrands, and 861 smokeless tobacco subbrands (4,942 total subbrands) must comply with section 904(a)(3) of the FD&C Act. Therefore, the total annualized burden for reporting company and product information is 3,296 hours.

Table 1 of this document also addresses the time required for manufacturers and importers to report quantities of HPHCs in their products. The burden hour estimates include the time needed to test the tobacco products, draft testing reports, draft the report for FDA, and submit the report to FDA. For cigarette filler, smokeless, and roll-your-own products, we estimate the burden to test the product, draft testing reports, draft the report for FDA, and submit the report to FDA to be 16,284 annualized burden hours. The burden for each product type reflects our estimate of the burden to test the tobacco products (i.e., carry out laboratory work).

In addition to addressing the time required to report quantities of HPHCs in tobacco products, table 1 of this document addresses the time required for manufacturers and importers to report quantities for HPHCs in cigarette smoke. The burden estimates include testing the tobacco products, drafting testing reports, drafting the report for FDA, and submitting the report to FDA. We estimate the annualized burden for this section to be 57,304 hours. The annualized burden reflects our estimate of the burden to test the tobacco products (i.e., carry out laboratory work). The burden estimate assumes that manufacturers and importers report HPHC quantities in cigarette mainstream smoke according to the two recommended smoking regimens. The total annualized burden for part one of table 1 (section 904(a)(3) reporting) is 76,884 hours.

Table 1 of this document also contains estimates for new product information received annually under section 904(c)(1) of the FD&C Act. Manufacturers and importers must report HPHC information under section 904(c)(1) of the FD&C Act at least 90 days prior to delivery for introduction into interstate commerce. We estimate that approximately 15 percent of FDA currently regulated tobacco products in any given year will require submission of this information. The estimated total annual burden for section 904(c)(1) of the FD&C Act is 11,550 hours, which includes reporting manufacturer/importer company and product information, reporting HPHC quantities in products, and reporting HPHC quantities in mainstream smoke.

The estimated total annual burden for the reporting of HPHC under section 904(a)(3) and (c)(1) of the FD&C Act is 88,434 hours, which includes the section 904(a)(3) annualized reporting burden plus the section 904(c)(1) annual reporting burden.

We have not estimated any capital costs because we do not believe there are any capital costs associated with this collection. However, you may comment on any specific capital costs that you have identified.

Dated: July 24, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2012–18442 Filed 7–27–12; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2012–N–0001]**

### Pediatric Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Pediatric Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the Agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on September 11, 2012, from 8:30 a.m. to 4 p.m.

*Location:* DoubleTree by Hilton Hotel, 8727 Colesville Rd., Silver Spring, MD 20910. The hotel's telephone number is 301–589–5200.

*Contact Person:* Walter Ellenberg, Office of Pediatric Therapeutics, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5154, Silver Spring, MD. 20993, 301–796–0885, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), to find out further information regarding FDA advisory committee information. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

*Agenda:* On September 11, 2012, the Pediatric Advisory Committee will meet to discuss pediatric-focused safety reviews, as mandated by the Best Pharmaceuticals for Children Act (Public Law 107–109) and the Pediatric Research Equity Act (Public Law 108–155), for Kapvay (clonidine hydrochloride), Vyvanse (lisdexamfetamine dimesylate), Ofirmev (acetaminophen), ella (ulipristal acetate), Beyaz (drospirenone/ethinyl estradiol/levomefolate calcium tablets and levomefolate calcium tablets), Lo