physician certification requirements were included in the law to ensure that patients require a level of care that is covered by the Medicare program and because the physician is a key figure in determining the utilization of health services. *Form Number:* CMS–R–5 (OMB control number: 0938–0454); *Frequency:* Occasionally; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 2,711,136; *Total Annual Responses:* 2,711,136; *Total Annual Hours:* 624,515. (For policy questions regarding this collection contact Kia Sidbury at 410–786–7816.)

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Program/Home Health Prospective Payment System Rate Update for Calendar Year 2010: Physician Narrative Requirement and Supporting Regulation; *Use:* Section (o) of the Act (42 U.S.C. 1395x) specifies certain requirements that a home health agency must meet to participate in the Medicare program. To qualify for Medicare coverage of home health services a Medicare beneficiary must meet each of the following requirements as stipulated in § 409.42: Be confined to the home or an institution that is not a hospital, SNF, or nursing facility as defined in sections 1861(e)(1), 1819(a)(1) or 1919 of Act; be under the care of a physician as described in § 409.42(b); be under a plan of care that meets the requirements specified in § 409.43; the care must be furnished by or under arrangements made by a participating HHA, and the beneficiary must be in need of skilled services as described in § 409.42(c). Subsection 409.42(c) of our regulations requires that the beneficiary need at least one of the following services as certified by a physician in accordance with § 424.22: Intermittent skilled nursing services and the need for skilled services which meet the criteria in § 409.32; Physical therapy which meets the requirements of § 409.44(c), Speech-language pathology which meets the requirements of § 409.44(c); or have a continuing need for occupational therapy that meets the requirements of § 409.44(c), subject to the limitations described in § 409.42(c)(4). On March 23, 2010, the Affordable Care Act of 2010 (Pub. L. 111–148) was enacted. Section 6407(a) (amended by section 10605) of the Affordable Care Act amends the requirements for physician certification of home health services contained in Sections 1814(a)(2)(C) and 1835(a)(2)(A) by requiring that, prior to certifying a patient as eligible for Medicare's home health benefit, the physician must document that the physician himself or herself or a permitted non-physician practitioner has had a face-to-face encounter (including through the use of tele-health services, subject to the requirements in section 1834(m) of the Act)'', with the patient. The Affordable Care Act provision does not amend the statutory requirement that a physician must certify a patient's eligibility for Medicare's home health benefit, (see Sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act. *Form Number:* CMS–10311 (OMB control number: 0938–1083); *Frequency:* Yearly; *Affected Public:* Business or other for-profits; *Number of Respondents:* 345,600; *Total Annual Responses:* 345,600; *Total Annual Hours:* 28,800. (For policy questions regarding this collection contact Hillary Loeffler at 410–786–0456.)

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Documentation Requirements Concerning Emergency and Nonemergency Ambulance Transports Described in the Beneficiary Signature Regulations in 42 CFR 424.36(b); *Use:* The statutory authority requiring a beneficiary's signature on a claim submitted by a provider is located in section 1835(a) and in 1814(a) of the Social Security Act (the Act), for Part B and Part A services, respectively. The authority requiring a beneficiary's signature for supplier claims is implicit in sections 1842(b)(3)(B)(ii) and in 1848(g)(4) of the Act. Federal regulations at 42 CFR 424.32(a)(3) state that all claims must be signed by the beneficiary or on behalf of the beneficiary (in accordance with 424.36). Section 424.36(a) states that the beneficiary's signature is required on a claim unless the beneficiary has died or the provisions of 424.36(b), (c), or (d) apply. We believe that for emergency and nonemergency ambulance transport services, where the beneficiary is physically or mentally incapable of signing the claim (and the beneficiary's authorized representative is unavailable or unwilling to sign the claim), that it is impractical and infeasible to require an ambulance provider or supplier to later locate the beneficiary or the person authorized to sign on behalf of the beneficiary, before submitting the claim to Medicare for payment. Therefore, we created an exception to the beneficiary signature requirement with respect to emergency and nonemergency ambulance transport services, where the beneficiary is physically or mentally incapable of signing the claim, and if certain documentation requirements are met. Thus, we added subsection (6) to paragraph (b) of 42 CFR 424.36. The information required in this ICR is needed to help ensure that services were in fact rendered and were rendered as billed. *Form Number:* CMS–10242 (OMB control number: 0938–1049); *Frequency:* Yearly; *Affected Public:* Business or other for-profits, Not-for-profit institutions); *Number of Respondents:* 10,402; *Total Annual Responses:* 14,155,617; *Total Annual Hours:* 1,180,578. (For policy questions regarding this collection contact Martha Kuespert at 410–786–4605.)

Dated: October 4, 2016.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2016–24341 Filed 10–6–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2872]

Medical Device User Fee Amendments; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting entitled ''Medical Device User Fee Amendments.'' The purpose of the meeting is to discuss proposed recommendations for the reauthorization of the Medical Device User Fee Amendments (MDUFA) for fiscal years (FYs) 2018 through 2022. MDUFA authorizes FDA to collect fees and use them for the process for the review of medical device applications. The current legislative authority for MDUFA expires October 1, 2017. At that time, new legislation will be required for FDA to continue collecting medical device user fees in future fiscal years. Following discussions with the device industry and periodic consultations with public stakeholders, the Federal Food, Drug, and Cosmetic Act (the FD&C Act) directs FDA to publish the recommendations for the reauthorized program in the **Federal Register,** hold a meeting at which the public may present its views on such recommendations, and provide for a period of 30 days for the public to provide written comments on such recommendations. FDA will then

consider such public views and comments and revise such recommendations as necessary.

DATES: The public meeting will be held on November 2, 2016, from 9 a.m. to 5 p.m. Submit electronic or written comments to the public docket by November 14, 2016. When the materials are available, they will be in the docket and posted on this Web site at: *http://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFee/ucm454039.htm.* See REGISTRATION section below regarding how to register for this public meeting.

ADDRESSES: The public meeting will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–N–2872 for ''Medical Device User Fee Amendments; Public Meeting.'' The commitment letter and proposed statutory changes are expected to be made public in mid-October. At that time, the materials will be posted in the docket and on this Web site at: *http://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFee/ucm454039.htm.* The docket will close on November 14, 2016. Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly available at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Aaron Josephson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5449, Silver Spring, MD 20993, 301–796–5178, *Aaron.Josephson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing its intention to hold a public meeting to discuss proposed recommendations for the reauthorization of MDUFA, which authorizes FDA to collect user fees and use them for the process for the review of device applications until September 30, 2017. Without new legislation, FDA will no longer be able to collect user fees for future fiscal years to provide funds for the process for the review of device applications. As required by section 738A(b)(2), (3), and (6) of the FD&C Act (21 U.S.C. 379j-1(b)(2), (3), and (6)), FDA obtained prior public input and negotiated an agreement with regulated industry while periodically consulting with patient and consumer advocacy groups and making minutes of negotiation and stakeholder meetings publicly available. Section 738A(b)(4) of the FD&C Act requires that, after holding negotiations with regulated industry and before transmitting the Agency's final recommendations to Congress for the reauthorized program (MDUFA IV), we do the following: (1) Present the draft recommendations to the Committee on Energy and Commerce of the U.S. House of Representatives and the Committee on Health, Education, Labor, and Pensions of the U.S. Senate; (2) publish the draft recommendations in the **Federal Register;** (3) provide a period of 30 days for the public to submit written comments on the draft recommendations; (4) hold a meeting at which the public may present its views on the draft recommendations; and (5) after consideration of public views and comments, revise the draft recommendations as necessary. This notice, the 30-day comment period, and the public meeting will satisfy certain of

these requirements. After the public meeting, we will revise the draft recommendations as necessary. In addition, the Agency will present the draft recommendations to the Congressional committees.

The purpose of the meeting is for the public to present its views on the draft recommendations for the reauthorized program (MDUFA IV). In general, the meeting format will include a brief presentation by FDA, but will focus on hearing from different stakeholder interest groups (such as patient advocates, consumer advocates, industry, health care professionals, and scientific and academic experts). The Agency will also provide an opportunity for individuals to make presentations at the meeting and for organizations and individuals to submit written comments to the docket before and after the meeting. The following information is provided to help potential meeting participants better understand the history and evolution of the medical device user fee program and the current status of the MDUFA IV draft recommendations.

II. What is MDUFA and what does it do?

MDUFA is the law that authorizes FDA to collect fees from device companies that register their establishments, submit applications to market devices, and make other types of submissions. In the years preceding enactment of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Pub. L. 107–250), FDA's medical device program suffered a long-term, significant loss of resources that undermined the program's capacity and performance. MDUFMA was enacted ''in order to provide FDA with the resources necessary to better review medical devices, to enact needed regulatory reforms so that medical device manufacturers can bring their safe and effective devices to the American people at an earlier point in time, and to ensure that reprocessed medical devices are as safe and effective as original devices.'' H.R. Rep. 107–728 at p. 21 (Oct. 7, 2002). MDUFMA was authorized for 5 years and contained two important features that relate to reauthorization:

- User fees for the review of medical device premarket applications, reports, supplements, and premarket notification submissions provided additional resources to make FDA reviews more timely, predictable, and transparent to applicants. User fees and appropriations for the medical device program helped FDA expand available expertise, modernized its information management systems, provided new review options, and provided more guidance to prospective submitters. The ultimate goal was for FDA to clear and approve safe and effective medical devices more rapidly, benefiting applicants, the health care community, and most importantly, patients.
- Negotiated performance goals for many types of premarket reviews provided FDA with benchmarks for measuring review improvements. These quantifiable goals became more demanding each year and included FDA decision goals and cycle goals (cycle goals refer to FDA actions prior to a final action on a submission). Under MDUFMA, FDA also agreed to several other commitments that did not have specific timeframes or direct measures of performance, such as expanding the use of meetings with industry, maintenance of current performance in review areas where specific performance goals had not been identified, and publication of additional guidance documents.

Medical device user fees and increased appropriations were viewed by FDA, Congress, and industry stakeholders as essential to support high-quality, timely medical device reviews, and other activities critical to the device review program.

MDUFMA provided for—and reauthorizations have maintained—fee discounts and waivers for qualifying small businesses. Small businesses make up a large proportion of the medical device industry, and these discounts and waivers helped reduce the financial impact of user fees on this sector of the device industry, which plays an important role in fostering innovation.

Since MDUFMA was first enacted in 2002, it has been reauthorized twice (the 2007 Medical Device User Fee Amendments (MDUFA II) and the 2012 Medical Device User Fee Amendments (MDUFA III)). Under MDUFA III, which has been in effect since 2012 and will expire on October 1, 2017, FDA has met or exceeded nearly all submission performance goals while implementing program enhancements designed to ensure more timely access to safe and effective medical devices. Information about FDA's performance is available in the yearly and quarterly MDUFA performance reports, which are online at: *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/UCM2007450.htm and http://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFee/ucm452535.htm.*

User fees and related performance goals have played an important role in providing resources and supporting the management systems for ensuring that safe and effective medical devices are available to patients in a timely manner.

III. Proposed MDUFA IV Recommendations

In preparing the proposed recommendations to Congress for MDUFA reauthorization, FDA conducted discussions with the device industry and consulted with stakeholders, as required by the FD&C Act. The Agency began the MDUFA reauthorization process by publishing a notice in the **Federal Register** requesting public input on the reauthorization and announcing a public meeting that was held on July 13, 2015. The meeting included presentations by FDA and a series of panels with representatives of different stakeholder groups, including patient and consumer advocacy groups, regulated industry, and health care professionals. The materials from the meeting, including a transcript and Webcast recording, can be found at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm445541.htm.*

From September 2015 through August 2016, FDA conducted negotiations with representatives of the device industry: The Advanced Medical Technology Association; the Medical Device Manufacturers Association; the Medical Imaging and Technology Alliance; and, the American Clinical Laboratory Association. During its negotiations with the regulated industry, FDA also held monthly consultations with stakeholders representing patient and consumer interests. As directed by Congress, FDA posted minutes of these meetings on its Web site at: *http://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFee/ucm454039.htm.*

The proposed recommendations for MDUFA IV address many priorities identified by public stakeholders, the device industry, and FDA. While some of the proposed recommendations are new, many either build on successful enhancements or refine elements from the existing program. FDA intends to post the full text of the proposed MDUFA IV commitment letter and proposed statutory changes at: *http://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFee/ucm454039.htm* before the public meeting. Each recommendation is briefly described with reference to the applicable section of the draft commitment letter.

A. Shared Outcome Goals

FDA and representatives of the device industry believe that the process

improvements outlined in the draft commitment letter, when implemented by all parties as intended, should further reduce the average Total Time to Decision for PMA applications and 510(k) submissions, provided that the total funding of the device review program adheres to the assumptions underlying the agreement. Reducing average Total Time to Decision is an important aspect of the ultimate goal of the user fee program, so that safe and effective devices reach patients and health care professionals more quickly. FDA will continue reporting, on an annual basis, the average Total Time to Decision, as defined in the draft commitment letter, for PMA and 510(k) submissions, with shared outcome goals for FDA and industry that reach 290 calendar days for PMAs and 108 calendar days for 510(k)s by FY 2022. Additional details regarding the shared outcome goals can be found in section I of the draft commitment letter.

B. Pre-Submissions

FDA will improve the pre-submission process and ramp up to a performance goal for written feedback on at least 1,950 pre-submissions within 70 days or 5 calendar days prior to the scheduled meeting, whichever comes sooner, in FY2022 (which is equivalent to meeting the stated timeline for at least 83 percent of an assumed 2,350 pre-submissions). Industry will be responsible for providing draft meeting minutes within 15 days of the meeting. Additional details regarding pre-submissions can be found in section II.A. of the draft commitment letter.

C. PMAs

FDA will maintain MDUFA III performance goals for all PMA submissions, including supplements. Additionally, as resources permit, FDA will issue a MDUFA decision within 60 days of an advisory committee recommendation and will issue a decision within 60 days of an applicant's response to an approvable letter. Additional details regarding PMAs can be found in sections II.B.-D. of the draft commitment letter.

D. De Novos

FDA will ramp up to a performance goal for reaching a decision on 70 percent of de novo submissions within 150 days in FY2022. Additional details regarding de novo submissions can be found in section II.E. of the draft commitment letter.

E. 510(k)s

FDA will maintain MDUFA III performance goals for all 510(k) submissions. Additionally, FDA will report performance separately for those reviewed by accredited Third Parties. Additional details regarding 510(k)s can be found in section II.F. of the draft commitment letter.

F. Clinical Laboratory Improvement Amendments (CLIA) Waiver by Application Submissions

FDA will improve the CLIA waiver by application process by establishing a centralized program management group within the Office of In Vitro Diagnostics and Radiological Health, implementing a Missed MDUFA Decision provision, hosting CLIA Waiver vendor days, and further reducing review times for CLIA Waiver by Application Submissions. Additional resources have not been included in the MDUFA agreement for CLIA Waiver applications. Additional details regarding CLIA Waiver by Application Submissions can be found in section II.G. of the draft commitment letter.

G. Quality Management

FDA will establish a dedicated premarket Quality Management team, which will be responsible for establishing a quality management framework for the premarket submission process in the Center for Devices and Radiological Health (CDRH) and conducting routine quality audits. Additional details regarding Quality Management can be found in section III.A. of the draft commitment letter.

H. Employee Recruitment and Retention

FDA will implement a more effective recruiting and hiring strategy and will improve employee retention by applying user fee revenues to retain high performing supervisors. Additional details regarding recruitment and retention can be found in section III.B. of the draft commitment letter.

I. Information Technology (IT)

FDA will implement IT improvements that correspond to new performance goals and reporting, enhance IT infrastructure to enable collection and reporting on structured data, develop and maintain a secure Web-based application that allows sponsors to view individual submission status in near real time, and develop structured electronic submission templates as a tool to guide industry's preparation of premarket submissions. Additional details regarding IT can be found in section III.C. of the draft commitment letter.

J. Enhanced Use of Consensus Standards

FDA and industry will establish a conformity assessment program for accredited testing laboratories that evaluate medical devices according to certain FDA-recognized standards. Additional details regarding the enhanced use of consensus standards can be found in section IV.D. of the draft commitment letter.

K. Third Party Premarket Review Program

FDA will strengthen the accredited person (Third Party) Premarket Review Program by offering improved training to Third Party review entities, redacting predicate review memos for use by third parties during their reviews, conducting audits of Third Party review quality, and publishing performance of individual Third Party entities, with the goal of eliminating routine re-review by FDA of Third Party reviews. Additional details regarding the Third Party Premarket Review Program can be found in section IV.E. of the draft commitment letter.

L. Patient Engagement

FDA will develop internal expertise on patient preference information and patient reported outcomes (PROs) to enhance the utility of such information in premarket submissions, publish a PRO validation guidance, and hold one or more public meetings. Additional details regarding patient engagement can be found in section IV.F. of the draft commitment letter.

M. Real World Evidence (RWE)

FDA will provide funding for the National Evaluation System for Health Technology to conduct pilots to establish the value of real RWE in the premarket program. Additional details regarding RWE can be found in section IV.H. of the draft commitment letter.

N. Digital Health

FDA will establish a centralized Digital Health unit to improve consistency in review of software as a medical device and software in a medical device, streamline and align FDA review processes with software life cycles, continue engagement in international harmonization efforts related to software review, and conduct other activities related to Digital Health. Additional details regarding Digital Health can be found in section IV.I. of the draft commitment letter.

O. Independent Assessment

FDA and industry will participate in an independent assessment of the CDRH

process for the review of device applications, including a more complete assessment of MDUFA III improvements and outcomes as well as an assessment of the effectiveness of the MDUFA IV programs. Additional details regarding the Independent Assessment can be found in section V. of the draft commitment letter.

P. Performance Reports

FDA will continue to report quarterly on performance against commitments. Additionally, FDA will separately report the number and percent of laboratory developed test (LDT) marketing applications completed within the performance goal for 510(k), de novo, and PMA submissions. FDA committed to treating LDTs no less favorably than other devices to which MDUFA performance goals apply. Additional details regarding performance reporting can be found in section VI. of the draft commitment letter.

In conjunction with the proposed enhancements and performance goals outlined in the draft commitment letter, FDA and industry agreed to the following proposed changes to the FD&C Act to ensure that FDA has the statutory authorities needed to implement the negotiated programmatic enhancements:

- FDA and industry are proposing to modify section 738(a)(2)(A) of the FD&C Act (21 U.S.C. 379j(a)(2)(A)) to allow for fees to be collected for de novo submissions and exempting de novo submissions from fees when solely for pediatric conditions for use (section 738(a)(2)(B)(v)(I)).
- FDA and industry are proposing to modify section 738(c) of the FD&C Act to reflect the negotiated fee setting structure. This negotiated structure allows FDA to collect inflation-adjusted base fee amounts without any reduction in fees in the event that submission or registration volumes are higher than planned. Any further adjustments beyond inflation would only be necessary if projected submission or registration volumes are lower than planned such that base fee amounts would need to be increased in order to generate the authorized total fee revenue in a given year.
- The statutory total revenue amounts and base fee amounts are proposed in FY2015 dollars such that annual inflation adjustments will be used to inflate FY2015 dollars to the appropriate amounts for each fiscal year in MDUFA IV.
- FDA is proposing to modify section 738(h)(1)(A) of the FD&C Act to update the appropriations trigger to provide assurance to industry that user fees will be additive to budget authority appropriations.
- FDA and industry are proposing to delete section 738(i)(4) of the FD&C Act to eliminate the fifth-year fee offset because the negotiated fee setting structure allows FDA to collect and use inflation-adjusted base fee amounts each year without any reduction in fees due to increased submission volume. Deleting the fee offset provision (section 738(i)(4)) is necessary to implement the negotiated fee setting structure.
- FDA and industry are proposing to add a subsection (d) to section 514 of the FD&C Act (21 U.S.C. 360d) (Performance standards) to provide authority for FDA to establish a conformity assessment program and per the agreements made during the user fee reauthorization negotiations. FDA and industry are proposing to amend section 523 of the FD&C Act (21 U.S.C. 360m) (Accredited persons) to provide FDA authority to tailor the scope of the Third Party review program per the agreements made during the user fee reauthorization negotiations.
- FDA and industry are proposing to amend section 741 of the FD&C Act (21 U.S.C. 379k–1) (Electronic format for submissions) to provide FDA the authority to develop and implement electronic submissions per the agreements made during the user fee reauthorization negotiations.

FDA will post the agenda approximately 5 days before the meeting at: *http://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFee/ucm454039.htm.*

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending the MDUFA meeting must register online by 4 p.m. October 26, 2016. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permit onsite registration on the day of the meeting, it will be provided beginning at 8 a.m.

If you need special accommodations because of a disability, please contact Joshua St. Pierre, 301–796–9587 or *Joshua.StPierre@fda.hhs.gov* no later than October 19, 2016.

To register for the meeting, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this meeting/public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, email, and telephone number. Those without Internet access should contact Aaron Josephson to register (see **FOR FURTHER INFORMATION CONTACT**). Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the meeting: This meeting will also be Webcast. The Webcast link will be available on the registration Web page after October 26, 2016. Organizations are requested to register all participants, but to view using one connection per location. If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *http://www.adobe.com/go/connectpro_overview.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register,** but Web sites are subject to change over time.

Requests to Present: This meeting includes a public comment session and topic-focused sessions. During online registration you may indicate if you wish to present and which topics you wish to address during the public comment session. FDA has included general topics in this document. FDA will do its best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation. Following the close of registration, FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by October 28, 2016. All requests to make oral presentations must be received by the close of registration on October 26, 2016, at 4 p.m. No commercial or promotional material will be permitted to be presented or distributed at the meeting.

FDA is holding this meeting to provide information on the proposed recommendations for the reauthorization of the MDUFA for FYs 2018 through 2022. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the meeting topics. The docket will open when the draft commitment letter and proposed statutory changes are made public, which is expected to be in mid-October. The materials will be posted on this Web site at: *http://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFee/ucm454039.htm.*

The docket will close 30 days after those documents are posted.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at in the docket at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (see **ADDRESSES**). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at *http://www.fda.gov.* A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at *http://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFee/ucm454039.htm.* (Select this meeting from the posted events list).

Dated: October 3, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–24237 Filed 10–6–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Data Use Agreement and Supplement for 2014 Health Center Patient Survey

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than November 7, 2016.

ADDRESSES: Submit your comments, including the ICR title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Data Use Agreement and Supplement for 2014 Health Center Patient Survey.

OMB No.: 0906–xxxx—NEW.

Abstract: The Health Center Patient Survey (HCPS), sponsored by HRSA's Bureau of Primary Health Care (BPHC), surveyed patients who use health centers funded under Section 330 of the Public Health Service Act. HCPS collects data on health center patients' sociodemographic characteristics, health conditions, health behaviors, access to and utilization of health care services, and satisfaction with health care. Survey results come from in-person, one-on-one interviews with patients and are nationally representative of the Health Center program patient population. To inform BPHC and HHS policy, funding, and planning decisions, the survey investigated how well HRSA-supported sites meet health care needs of the medically underserved and assessed how patients perceive the quality of their care.

The HCPS is unique because it focuses on comprehensive patient-level data. These and other features of the data will provide researchers and policymakers the capacity to empirically explore policy relevant topics relevant to the Health Center program using up-to-date information.

Prior to releasing this information, BPHC will request prospective users to fill out a ''Data Use Agreement'' (DUA). BPHC uses DUAs as legal binding agreements when an external entity (*e.g.,* contractor, private industry, academic institution, other federal government agency, or state agency) requests the use of BPHC personally/organizationally identifiable data that is covered by the Privacy Act of 1974. The agreement delineates the confidentiality requirements of the Privacy Act, security safeguards, and BPHC's data use policies and procedures. The DUA will serve as both a means of informing data users of these requirements and a means of obtaining their agreement to abide by these requirements.

Need and Proposed Use of the Information: Before allowing access to unrestricted data that contains sensitive grantee and patient information that is protected by the Privacy Act of 1974, prospective users will submit a signed DUA and describe what proposed research they intend to undertake in using the dataset. A BPHC workgroup will determine whether the project is an appropriate and legitimate use of the data. The criteria to determine admissible projects will include: (1) Relevance of the topic of study to BPHC/HHS policy; (2) feasibility of the project given the parameters described in DUA supplemental; and (3) the proposed end-use of the research that will be undertaken.

Likely Respondents: Prospective researchers in academia, private contractors, and Primary Care Associations/Health Center grantee organizations.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
DUA	20	1	20	0.25	5
DUA Supplemental	20	1	20	1.25	25
Total	40	.....	40	.....	30