GDUFA II also includes a pre-ANDA program to clarify regulatory expectations for complex generic product developers early in product development and during application review.

Additional information concerning GDUFA, including the text of the law, the GDUFA II Commitment Letter, key **Federal Register** documents, GDUFA-related guidances, performance reports, and financial reports may be found on the FDA website at *https://www.fda.gov/gdufa.*

II. Topics for Discussion at the Public Meeting

FDA is interested in responses to the following general questions:

- What is your assessment of the overall performance of the GDUFA program to date?
- What aspects of GDUFA should be retained, changed, or discontinued to further strengthen and improve the program?
- What new features should FDA consider adding to the program to enhance efficiency and effectiveness of the generic drug review process?

FDA welcomes any other relevant information the public would like to share as it relates to the GDUFA program, including but not limited to the following topic areas:

- supply chain security and drug shortages;
- drug quality and advanced manufacturing; and
- complex products.

In general, the public meeting's format will include presentations by FDA and our stakeholders, which may include scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups, the generic drug industry, and the general public. The amount of time available for public testimony will be determined by the number of persons who register to present during the virtual public meeting. A draft agenda and other background information for the public meeting will be posted at *https://www.fda.gov/gdufa* by July 14, 2020.

III. Participating in the Public Meeting

Registration: FDA is seeking participation (*i.e.,* oral remote presentations) during the virtual public meeting by all interested parties, including but not limited to scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups, the generic drug industry, and the general public. Persons interested in attending this virtual public meeting should register online by 11:59 p.m. Eastern Time on July 7, 2020, at *https://collaboration.fda.gov/e8a35s83so0x/event/registration.html.* Please provide complete contact information for each attendee, including name, title, affiliation, and email.

Requests for Oral Presentations: If you wish to present during a public comment session or participate in a specific session, please submit your request to *GenericDrugPolicy@fda.hhs.gov* by 11:59 p.m. Eastern Time on July 7, 2020. Your email should contain which topic(s) you wish to address and include complete contact information, including name, title, affiliation, address, and email address. We will do our best to accommodate requests to make public comments and requests to participate in specific sessions. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, we 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 July 8, 2020. All requests to make oral presentations must be received by the close of registration on July 7, 2020, 11:59 p.m. Eastern Time. If selected for presentation, any presentation materials must be emailed to *GenericDrugPolicy@fda.hhs.gov* no later than July 14, 2020. No commercial or promotional material will be permitted to be presented or distributed during the virtual public meeting.

Streaming Webcast of the Public Meeting: This virtual public meeting will be accessible via webcast only. In order to connect to the webcast, you must have Adobe Connect. The link for the webcast will be sent to all registered attendees in advance of the event.

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 *https://www.adobe.com/go/connectpro_overview.* FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https://www.fda.gov/gdufa.*

Dated: June 22, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–13749 Filed 6–25–20; 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; Information Collection Request Title: Membership Forms for Organ Procurement and Transplantation Network OMB No. 0915–0184–Revision

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

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA has 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. OMB may act on HRSA's ICR only after the 30 day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than July 27, 2020.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under—Open for Public Comments'' or by using the search function.

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

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Membership Forms for Organ Procurement and Transplantation Network OMB No. 0915–0184–Revision.

Abstract: This is a request for OMB approval for revisions of the application documents used to collect information for determining if the interested party is compliant with membership requirements contained in the final rule Governing the Operation of the Organ Procurement and Transplantation Network (OPTN), (42 CFR part 121) ''the OPTN final rule.''

A 60-day notice published in the **Federal Register** on February 13, 2020, vol. 85, No. 30; pp. 8300–02. There were no public comments.

Need and Proposed Use of the Information: Membership in the OPTN is determined by submission of application materials to the OPTN (not to HRSA) demonstrating that the applicant meets all required criteria for membership and will agree to comply with all applicable provisions of the National Organ Transplant Act, as amended, 42 U.S.C. 273, *et seq.,* the OPTN final rule, OPTN Policies, and OPTN Bylaws. Section 1138 of the Social Security Act, as amended, 42 U.S.C. 1320b–8 (section 1138) requires that hospitals in which transplants are performed by members of, and abide by, the rules and requirements of the OPTN (that have been approved by the Secretary of HHS) as a condition of participation in Medicare and Medicaid.

Proposed Revisions to OPTN Membership Applications: Changes to the forms are proposed to make application requirements more clear and organized, and thus less cumbersome for applicants to complete. Proposed revisions include changes to wording to make questions more consistent with the language of the OPTN Bylaws (Bylaws). In addition, the applications have been revised so that the sequence of questions is parallel to that of the Bylaws. Using the Bylaws as a baseline, the revamped applications have been constructed in parallel order of the Bylaws so that an applicant can have the application and Bylaws side-by-side for easy reference. Additional proposed changes to the application include:

- A few major changes were made to the application order of documentation and attachments. The embedded transplant logs were revised in the form of a 'universal' surgeon and physician log that will be provided as a separate attachment to the application. This new log will provide applicants with all OPTN Bylaws requirements. We hope the added technology utilized in the log will help applicants complete the log with limited errors.
- Also within the applications, ''checkboxes''—fillable tables that were not checkboxes at all—were removed, and working checkboxes were inserted. The ''narrative'' section was replaced by checkbox attestations, which will serve the same purpose—understanding relevant and recent surgeon and physician applicant experience.
- The previous membership applications had several places for the applicants to sign. The new application requests only one signature from each member applicant involved.
- Additional changes to the application process include streamlining previous application attachments for key personnel and living donor components into one form for the respective organ application.
- Pediatric Bylaw Requirements, where applicable, were also given their sections within the organ applications. Conversely, the Certificate of Assessment (formerly known as Certificate of Investigation) and the Primary Coverage Plan Checklist was pulled out of the previous organ-specific applications and given their own, separate attachment. These changes will allow OPTN application reviewers to give these application components to applicants in as few attachments as possible. These changes will also allow the United Network for Organ Sharing Membership Team to give these important application components to applicants in as few attachments as possible, but are inclusive of all possible changes within a program.
- Further changes have been made to the Vascularized Composite Allograft (VCA) Transplant program applications, which were previously submitted as separate applications for OMB approval based on body part transplanted. These forms have been revised into one single application with sections for each VCA organ type.
- Personnel changes for Organ Procurement Organizations (OPOs) and Histocompatibility Laboratories have also been consolidated into organization applications. OPO and Lab applicants will be able to use one respective application for new and/or personnel changes.

Given these changes, the overall burden has decreased significantly from an estimated 7,020 total burden hours to 4,755 hours in this current proposed revision package, although some forms have been combined into one more comprehensive form resulting in increased burden hours for a particular form.

Likely Respondents: Parties seeking initial OPTN membership approval and then maintenance of existing OPTN approval. Applicants include the following: Hospitals seeking to perform organ transplants, non-profit organizations seeking to become an organ procurement organization, and medical laboratories seeking to become an OPTN-approved histocompatibility laboratory. In addition, there are other OPTN membership categories for organizations and individuals who want to participate in the organ transplant system, and they are also required to fill out an appropriate application.

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
OPTN Membership Application for Transplant Hospitals	2	1	2	3	6
OPTN Certificate of Assessment and Program Coverage Plan Membership Application	2	1	2	3	6
OPTN Membership Application for Kidney Transplant Programs	189	2	378	3	1,134

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS—Continued

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
OPTN Membership Application for Liver Transplant Programs	110	2	220	3	660
OPTN Membership Application for Pancreas Transplant Programs	120	2	240	3	720
OPTN Membership Application for Heart Transplant Programs	142	2	284	3	852
OPTN Membership Application for Lung Transplant Programs	60	2	120	3	360
OPTN Membership Application for Islet Transplant Programs	4	2	8	2	16
OPTN Membership Application for Vascularized Composite Allograft (VCA) Transplant Programs	53	2	106	2	212
OPTN Membership Application for Intestine Transplant Programs	90	2	180	3	540
OPTN Membership Application for Organ Procurement Organizations (OPOs)	10	1	10	3	30
OPTN Membership Application for Histocompatibility Laboratories	27	2	54	3	162
OPTN Representative Form	20	2	40	1	40
OPTN Medical/Scientific Membership Application	7	1	7	1	7
OPTN Public Organization Membership Application	4	1	4	1	4
OPTN Business Membership Application	2	1	2	1	2
OPTN Individual Membership Application	4	1	4	1	4
OPTN Membership Application Surgeon or Physician Log*	.....	.....	.....	.....	.....
Total = 18 forms	846	.....	1,661	.....	4,755

*The OPTN Membership Application Surgeon or Physician Log accompanies every individual organ application. The burden to complete is built into the organ application data.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2020–13793 Filed 6–25–20; 8:45 am]

BILLING CODE 4165–15–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; Information Collection Request Title: Ryan White HIV/AIDS Program: Allocation and Expenditure Forms, OMB No. 0915–0318—Revision

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

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA has 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. OMB may act on HRSA's ICR only after the 30 day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than July 27, 2020.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

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

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Ryan White HIV/AIDS Program: Allocation and Expenditure Forms, OMB No. 0915–0318—Revision.

Abstract: HRSA's HIV/AIDS Bureau administers the Ryan White HIV/AIDS Program (RWHAP) authorized under Title XXVI of the Public Health Service Act as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009. RWHAP Allocation and Expenditure Reports (A&E Reports), in conjunction with the Consolidated List of Contractors (CLC), will allow HRSA to monitor and track the use of grant funds for compliance with program and grants policies and requirements as outlined in the 2009 legislation. To avoid duplication and reduce recipient reporting burden, HRSA created an electronic grantee contract management system (GCMS) that includes data required for various reports, including the Allocations Reports, the CLC and other HRSA data reports, such as the RWHAP Services Report. Recipients can access GCMS year-round to upload or manually enter data on their service provider contractors and subrecipients, the RWHAP core medical and support services provided, and their funding amounts. GCMS automatically repopulates the data required for the Allocations Reports and other reports. Expenditures Report data are not auto-populated in the GCMS, and are thus still manually reported in the data reporting system.

Allocations and Expenditures (A&E) Reports

Recipients funded under RWHAP Parts A, B, C, and D are required to report financial data to HRSA at the beginning (Allocations Report) and at the end of their grant budget period