(OMB Control Number: 0938–0679); *Frequency:* Occasionally; *Affected Public:* Individuals or Households; *Number of Respondents:* 462,000; *Total Annual Responses:* 462,000; *Total Annual Hours:* 418,563. (For policy questions regarding this collection contact Paula Smith at 410–786–4709.)

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Rate Increase Disclosure and Review Reporting Requirements; *Use:* Section 1003 of the Affordable Care Act adds a new section 2794 of the PHS Act which directs the Secretary of the Department of Health and Human Services (the Secretary), in conjunction with the states, to establish a process for the annual review of ''unreasonable increases in premiums for health insurance coverage.'' The statute provides that health insurance issuers must submit to the Secretary and the applicable state justifications for unreasonable premium increases prior to the implementation of the increases. Section 2794 also specifies that beginning with plan years beginning in 2014, the Secretary, in conjunction with the states, shall monitor premium increases of health insurance coverage offered through an Exchange and outside of an Exchange.

Section 2794 directs the Secretary to ensure the public disclosure of information and justification relating to unreasonable rate increases. Section 2794 requires that health insurance issuers submit justification for an unreasonable rate increase to CMS and the relevant state prior to its implementation. Additionally, section 2794 requires that rate increases effective in 2014 (submitted for review in 2013) be monitored by the Secretary, in conjunction with the states. To those ends, Section 154 of the CFR establishes various reporting requirements for health insurance issuers, including a Preliminary Justification for a proposed rate increase, a Final Justification for any rate increase determined by a state or CMS to be unreasonable, and a notification requirement for unreasonable rate increases which the issuer will not implement.

In order to obtain the information necessary to monitor premium increases of health insurance coverage offered through an Exchange and outside of an Exchange, 45 CFR 154.215 would require health insurance issuers to submit the Unified Rate Review Template for all single risk pool coverage products in the individual or small group (or merged) market, regardless of whether any plan within a product is subject to a rate increase. That regulation would also require health insurance issuers to submit an Actuarial Memorandum (in addition to the Unified Rate Review Template) when a plan within a product is subject to a rate increase. Although the two required documents are submitted at the risk pool level, the requirement to submit is based on increases at the plan level.

In order to conduct a review to assess reasonableness when a plan within a product has a rate increase that is subject to review, health insurance issuers would be required to submit a written description justifying the increase (in addition to the Unified Rate Review Template and Actuarial Memorandum). Although the required documents are submitted at the risk pool level, the requirement to submit is based on increases at the plan level. *Form Number:* CMS–10379 (OMB Control Number: 0938–1141); *Frequency:* Yearly; *Affected Public:* State and Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 1,081; *Total Annual Responses:* 1,621; *Total Annual Hours:* 17,837. (For policy questions regarding this collection contact Lisa Cuozzo at 410–786–1746.)

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medical Loss Ratio Annual Reports, MLR Notices, and Recordkeeping Requirements; *Use:* Under Section 2718 of the Affordable Care Act and implementing regulation at 45 CFR part 158, a health insurance issuer (issuer) offering group or individual health insurance coverage must submit a report to the Secretary concerning the amount the issuer spends each year on claims, quality improvement expenses, non-claims costs, Federal and State taxes and licensing and regulatory fees, the amount of earned premium, and beginning with the 2014 reporting year, the amounts related to the transitional reinsurance, risk adjustment, and risk corridors. An issuer must provide an annual rebate if the amount it spends on certain costs compared to its premium revenue (excluding Federal and States taxes and licensing and regulatory fees) does not meet a certain ratio, referred to as the medical loss ratio (MLR). Each issuer is required to submit annually MLR data, including information about any rebates it must provide, on a form prescribed by CMS, for each State in which the issuer conducts business. Each issuer is also required to provide a rebate notice to each policyholder that is owed a rebate and each subscriber of policyholders that are owed a rebate for any given MLR reporting year. Additionally, each issuer is required to maintain for a period of seven years all documents, records and other evidence that support the data included in each issuer's annual report to the Secretary. Under Section 1342 of the Patient Protection and Affordable Care Act and implementing regulation at 45 CFR part 153, issuers of qualified health plans (QHPs) must participate in a risk corridors program. A QHP issuer is required to pay charges to or receive payments from CMS based on the ratio of the issuer's allowable costs to the target amount. Each QHP issuer is required to submit an annual report to CMS concerning the issuer's allowable costs, allowable administrative costs, and the amount of premium.

The 2015 MLR Reporting Form and Instructions reflect changes for the 2015 reporting/benefit year and beyond. In 2016, it is expected that issuers will submit fewer reports and send fewer notices to policyholders and subscribers, which will reduce burden on issuers. On the other hand, it is expected that issuers will send more rebate checks in the mail to individual market policyholders, which will increase burden for some issuers. It is estimated that there will be a net reduction in total burden from 271,600 to 235,148. *Form Number:* CMS–10418 (OMB Control Number: 0938–1164); *Frequency:* Annually; *Affected Public:* Private Sector, Business or other for-profits and not-for-profit institutions; *Number of Respondents:* 538; *Number of Responses:* 2,818; *Total Annual Hours:* 235,148. (For policy questions regarding this collection contact Christina Whitefield at 301–492–4172.)

Dated: February 16, 2016.

William N. Parham, III,

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

[FR Doc. 2016–03474 Filed 2–18–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Native Employment Works (NEW) Program Plan Guidance and Native Employment Works (NEW) Program Report.

OMB No.: 0970–0174.

Description: The Native Employment Works (NEW) program plan is the

application for NEW program funding. As approved by the Department of Health and Human Services (HHS), it documents how the grantee will carry out its NEW program. The NEW program plan guidance provides instructions for preparing a NEW program plan and explains the process for plan submission every third year. There are two versions of this plan guidance: One for tribes that include their NEW program in a Public Law 102–477 project, and one for tribes that do not. The primary difference between the guidance documents is in the instructions for how to submit the plan. The NEW program report provides information on the activities and accomplishments of grantees' NEW programs. The NEW program report and instructions specify the program data that NEW grantees report annually.

Respondents: Federally recognized Indian Tribes and Tribal organizations that are NEW program grantees.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
NEW program plan guidance for non-477 Tribes	[1] 15	1	29	435
NEW program plan guidance for 477 Tribes	[2] 11	1	29	319
NEW program report	[3] 44	1	15	660

Estimated Total Annual Burden Hours: 1,414.

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20201. Attention Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2016–03460 Filed 2–18–16; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0310]

Guidance for Industry on Immunogenicity-Related Considerations for Low Molecular Weight Heparin; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Immunogenicity-Related Considerations for Low Molecular Weight Heparin.'' This guidance discusses how applicants for low molecular weight heparin (LMWH) products should provide information on impurities and their potential impact on immunogenicity.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: 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–2014–D–0310 for ''Immunogenicity-Related Considerations for Low Molecular Weight Heparin.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable 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