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; Affecte 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 program. A QHP issuer is required to provide an annual rebate if the amount it spends on claims, quality improvement expenses, non-claims costs, Federal and State taxes and licensing and regulatory fees (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.

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; Affecte 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 Report

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.

### 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_SUBLIMATION@OMB.EOP.GOV, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis, Reports Clearance Officer.

### 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 submission

### ANNUAL BURDEN ESTIMATES

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<th>Instrument</th>
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*Estimated Total Annual Burden Hours: 1,414.*

**Hours:**