DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Center for Consumer Information and Insurance Oversight
200 Independence Avenue SW
Washington, DC 20201

CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR CONSUMER INFORMATION & INSURANCE OVERSIGHT

OVERSIGHT GROUP

Date: February 5, 2016 – UPDATED May 4, 2016

To: Health Insurance Issuers in Missouri, Oklahoma, Texas, and Wyoming

RE: 2016 Form and Rate Filing Instructions and Health Insurance Oversight System (HIOS) Technical Assistance for Plan Year 2017

The Centers for Medicare & Medicaid Services (CMS) is responsible for enforcing provisions of title XXVII of the Public Health Service Act (PHS Act) with respect to health insurance issuers in the group and individual markets when a state informs CMS that it does not have authority to enforce or is not otherwise substantially enforcing one or more of the provisions. In addition, if a state does not have an effective rate review program, CMS will review a rate increase subject to review to determine whether it is unreasonable, as required by 45 CFR Part 154.

A. FORM FILING

1. Who must submit form filings to CMS for Plan Year 2017?

Health insurance issuers in Missouri, Oklahoma, Texas, and Wyoming must submit form filings for all products in the individual* and group markets, except for 1) excepted benefit products, such as stand-alone dental products, and other excepted benefits products; and 2) grandfathered products.

*Student health and accident plans are defined as individual market plans, and are subject to these requirements.

2. What is the difference between a product and a plan?

A **product** is a discrete package of health insurance coverage benefits that a health insurance issuer offers using a particular network type within a service area. Put another way, a **product** is any set of plans that share network type and set of benefits.

A **plan** is the pairing of the health insurance coverage benefits under the **product** with cost sharing levels, provider network, and service area. The **product** comprises all plans offered within the product. The combination of all service areas of the **plans** offered within a **product** constitutes the total service area of the product.

3. Where are form filings submitted?

Product forms must be submitted in the Health Insurance Oversight System (HIOS) Document Collection Form Filing Module at https://portal.cms.gov. Each product must be a separate submission. Each product submission must include all **plans** to be offered for that product. Note: a product may include QHP and Non-QHP plans. Follow the instructions below for where forms are to be filed based on whether the plan is QHP or Non-QHP. For example, a product that contains both QHP and Non-QHP plans will require submission of the Plan and Benefits templates for the QHP plans in the HIOS Plan Management and Market Wide Functions Module, and Plan and Benefits templates for the Non-QHP plans in the HIOS Document Collection Form Filing Module.

4. What documents need to be submitted in the HIOS Document Collection Form Filing Module?

Issuers offering products identified above must submit the following forms:

- Policy/Group Master Policy forms (one policy form for all plans within a product);
- Certificate/Evidence of Coverage forms (one certificate/evidence of coverage for all plans within a product);
- Schedule of Benefits/Summary of Benefits (one for each plan and silver plan variation within a product);
- Riders; Endorsements; Amendments;
- Summary of Benefits and Coverage (SBC) (one SBC per issuer for PPO/POS/EPO products and one per issuer for HMO products, if the issuer offers both PPO/POS/EPO and HMO products. For products that include plans designed to comply with metal level actuarial value requirements, please submit a Silver level plan SBC);
- Notices of Appeals and External Review Rights; and
- Explanation of Variability;
    - If plans include variable information (i.e., bracketed language), submit an explanation of variability into the HIOS Document Collection Form Filing Module.
    - If the variable limits are outside of the federally permitted limits for Plan Year 2017 (for example, the annual limitation on cost sharing in your Benefits Schedule indicates [$0 - $20,000]), submit a certification that the plan will not exceed the federal limitations for Plan Years beginning in 2017 into the HIOS Document Collection Form Filing Module.

5. QHP or Non-QHP?

a. In addition to the requirements specified in Question #4, for products that include plans for which the issuer applied for QHP certification, issuers must submit for each plan for which the issuer applied for QHP certification, Plan Management templates and justifications such as the Plan and Benefits Templates, Add-In files,

and Rx templates. Completed templates and justifications should be uploaded into the HIOS Plan Management and Market Wide Functions Module. Issuers can download these templates from the Center for Consumer Information & Insurance Oversight (CCIIO) website: http://cciio.cms.gov/programs/exchanges/qhp.html. Issuers should file all appropriate templates, justifications, and supporting documents as identified in the QHP application instructions. The information provided through the HIOS Plan Management and Market Wide Functions Module will be considered as part of the QHP application and reviewed by CMS for both compliance with the market reform provisions of the PHS Act and QHP certification processes and requirements.

b. In addition to the requirements specified in Question #4, for plans for which the issuer is not applying for QHP certification within products offered in the individual and small group markets,[1] issuers must submit the following into the HIOS Document Collection Form Filing Module:
    - Plan and Benefits Template;
    - CMS Prescription Drug Template (one template per product in Excel format);
    - Results of the Actuarial Value Calculator (screen shot or in Excel format);
    - Unique Plan Design Supporting Documentation and Justification, if applicable;
    - Essential Health Benefit Substituted Benefit (Actuarial Equivalent) Justification, if applicable; and
    - Formulary—Inadequate Category/Class Count Supporting Documentation and Justification, if applicable.

6. When is the Form Filing Submission Due?

- April 11, 2016: Form filing window opens
- May 11, 2016: Deadline for filing forms for all products, except for student health products and products offered in the large group market (off-Marketplace)
- 60 days prior to marketing: Deadline for filing forms for student health products and products offered in the large group market (off-Marketplace)

7. What are some general tips all issuers should keep in mind for their submissions?

a. As part of your form filing, identify whether each product will include any plans for which you will be applying for QHP certification, and identify the coverage level for each plan within a product (i.e., bronze, silver, gold,

[1] Under section 1312(f)(2)(B) of the Affordable Care Act, beginning in 2017, each state may allow issuers of health insurance coverage in the large group market in the state to offer QHPs in such market through a Marketplace. Nonetheless, the essential health benefits and actuarial value requirements are not applicable to plans for which the issuer is not applying for QHP certification within products offered in large group markets. Therefore, these documents are not required to be filed with CMS in the direct enforcement states for the large group market.

platinum, or catastrophic), if applicable. Also if a form is used for multiple products or plans, please indicate which forms belong with which products or plans.

b. Each file should be labeled with the appropriate name for identification (e.g., "RxtemplateQHP.xls" or RxJustificationQHP.xls"). The following are examples of acceptable Document Type fields:

- Contract – Group master policy or individual policy form;
- Contract Amendment – Amendments to the group master policy or individual policies;
- Policy Forms – Schedule of Benefits/Summary of Benefits;
- Certificates/Outlines of Coverage – Certificate/Evidence of Coverage;
- SBC – Summary of Benefits and Coverage;
- Supplemental Information – Plan and Benefits Template, Explanation of Variability, Certifications, Explanations;
- Rx Template – Pharmacy Template;
- AV Calculator – AV Calculator Screenshots;
- Justification – Unique Plan Design Supporting Documentation and Justification, Essential Health Benefit Substituted Benefit Justification, Formulary – Inadequate Category/Class Count Supporting Documentation and Justification;
- Policy Riders & Endorsements – Certificate/Evidence of Coverage Benefit Riders or Endorsements; and
- Notice Requirements – Notice of Appeals and External Review, and required federal notices, if applicable.

c. Please include in the file name for each document submitted if it is being submitted in connection with a plan for which you will be submitting a QHP certification application or not. For example: CertXXX_MO_2016_Silver_QHP or CertXXX_MO_2016_NQ.

d. If you decide during the CMS review process not to market a product or plan, please notify us by sending an email to FormFiling@cms.hhs.gov and include your issuer name, issuer state, HIOS issuer ID and submission ID of the form filing(s) affected.

8. What's new from last year?

Here are a few things to consider when submitting plan documents into the Document Collection Form Filing Module:

a. New data elements. There are new data elements displayed on the "Review Submission" and "Manage Submission" tabs. One data element allows for three possible statuses:

- Review Incomplete – The submission is open to the issuer. In this status, an issuer will be able to add or replace documents within the submission.
- Review In Progress – In this status, the submission will be locked to the issuer. The confirmed documents are under review by CMS. The issuer will not be able to add or replace documents until CMS moves the review to the "Review Incomplete" status. The issuer will receive notification when the status moves to "Review Incomplete".
- Review Complete – Submission is permanently locked. No changes can be made to the documents in the submission. An issuer will need to email CMS at formfiling@cms.hhs.gov if it needs to have the submission re-opened.

The next data element is the latest modification date. This is the date the issuer last modified (Retired, Replaced, or Added) a document.

b. New Essential Health Benefit Benchmark plans (EHB-Benchmark) for Plan Year 2017. Each state has a new EHB-Benchmark plan applicable for Plan Years beginning in 2017. Please be sure to review the updated EHB-Benchmark plan for the applicable state to ensure that forms meet the substantially equal requirements.

9. What were the most common issues found for Plan Year 2016 and how can issuers avoid them?

The following issues are common, yet easily avoided. Below each issue is guidance on how to avoid the issue for Plan Year 2017.

a. Essential Health Benefits (EHB). Under subpart B of 45 CFR part 156, which implements section 2707 of the PHS Act and section 1302 of the Affordable Care Act, non-grandfathered small group and individual market insurance coverage must provide coverage for the ten EHB categories. Many, if not all, products raise concerns with regard to compliance with this requirement.

- EHBs must be substantially equal to those found in the EHB-Benchmark plan, including all limitations and exclusions on the benefits. Be sure to include all EHB-Benchmark benefits in your product or provide the substitution information and actuarial justification.
- Lifetime and Annual dollar limits are not permitted on essential health benefits. It is not sufficient to simply assert the EHB-Benchmark plan uses similar limitations or that the limitations are part of a state mandated benefit. HHS regulations permit converting annual dollar limits to actuarially equivalent service or treatment limits.
- To the extent that product/plan documents do not explicitly indicate that the product covers pediatric vision and dental benefits that are substantially similar to the EHB-Benchmark, submit additional documentation to confirm that this coverage is included.

b. Fair Health Insurance Premiums. Under 45 CFR § 147.102(a)(1)(iv), which implements section 2701 of the PHS Act, an issuer of non-grandfathered coverage in the small group market may implement the tobacco use surcharge for enrollee premium rates only in connection with a wellness program (such as a tobacco cessation program) meeting the standards of section 2705 of the PHS Act and its implementing regulations. CMS will review small group market filings that include rates for tobacco use to ensure they include provisions regarding tobacco-related wellness programs. The terms of the wellness program will also be reviewed for compliance with section 2705 of the PHS Act and its implementing regulations.

c. Preventive Health Services. 45 CFR § 147.130, which implements section 2713 of the PHS Act, requires issuers of non-grandfathered coverage in the group and individual markets to include coverage of specified preventive health services without cost sharing. CMS will closely review issuers' policy forms to ensure coverage without cost sharing of the full list of applicable preventive services. This is accomplished by verifying that the policy form specifies coverage of each required preventive service. CMS will ensure that coverage is provided for at least one form of contraception in each of the methods identified for women by the Food and Drug Administration. CMS will also review to ensure that there is an easily accessible, transparent, and sufficiently expedient exceptions process for a contraceptive item or service to be covered without cost sharing if an individual's attending provider recommends a particular item or service based on a determination of medical necessity with respect to that individual.

d. Rx Template class count and non-discrimination reviews. Please run the Rx Class Count tool and Non-discrimination tool against your Rx template (2017, v 6.0) to ensure you have no discrepancies. If there are discrepancies, provide a detailed justification form to explain which drugs are used in the category or why you believe your plan is not discriminatory. The Rx review tools are available on the CCIIO website https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/qhp.html

e. Discriminatory benefit design. If there are age limits (or other similar limitations) for benefits within your form filing documents, we will flag these for possible discriminatory benefit design. It is not sufficient to simply assert that the EHB-Benchmark plan uses similar limitations or that the limitations are part of a state mandated benefit because EHB compliant plans must modify plan designs as necessary to comply with 45 CFR 156.125.

f. Clinical Trials. Routine patient care must be covered for clinical trials for cancer and other life threatening diseases. Be sure your clinical trials provision follows the federal definition for approved clinical trials (42 U.S.C. 300gg-8(d)(1)) and qualified individual (42 U.S.C. 300-gg-8(b)).

10. Is CMS offering additional opportunities to ask questions about Form Filing?

A breakout session on form filing and rate review submissions is scheduled during the Annual Qualified Health Plan Issuer Conference to be held March 2 – 4, 2016 at CMS in Baltimore, Maryland. You may register to attend in person or through remote access on RegTap (https://www.regtap.info/reg_events_view.php?class=227) Staff from the Compliance and Enforcement Division will be available during the March 2-4 QHP Issuer training at CMS Headquarters in Baltimore.

In addition, CMS will host a webinar to provide issuers with an opportunity to ask CMS questions pertaining to filing forms with CMS for review. No registration is required. Issuers can submit questions in advance of the training to FormFiling@cms.hhs.gov.

When: Friday, March 25, 2016 from 1 pm to 2 pm Eastern Time

Call access information:
1. Please call the following number: WebEx: 1-877-267-1577
2. Follow the instructions you hear on the phone.

Your WebEx Meeting Number: 995 055 448

To join this meeting online:

1. Go to https://meetings.cms.gov/orion/joinmeeting.do?MeetingKey=995055448
2. If requested, enter your name and email address.
3. Click "Join".
4. Follow the instructions that appear on your screen.

11. How do I use HIOS to submit a Form Filing?

HIOS is the federal document collection repository for form filing submissions.

To begin this process, issuers will need to register for access to the Health Insurance Oversight System (HIOS), request access to the Document Collection Form Filing Module, and choose the user role for their submission. One of the two mutually exclusive user roles must be selected: (1) Submitter, who completes the application and submits the documents, or (2) Certifying Official, who provides certification to select Submitter users with permission to confirm application submissions to CMS for review.

a. New HIOS users:

i. Register for a CMS EIDM Account:
   1. Navigate to the CMS Enterprise Portal (https://portal.cms.gov) and click "New User Registration" on the right side of the page.

2. Accept the Terms and Conditions.

3. Enter the required personal information and choose the desired User ID and Password. The User ID uniquely identifies the user to EIDM, and therefore cannot be changed. Based on the information provided, users will be required to answer questions for identity verification. This information is submitted to Experian and unique questions and answers are provided for identity proofing. After completing the registration process, an email acknowledging successful registration to EIDM will be sent to the user, along with the User ID.

ii. Register for a HIOS Account:

1. Navigate to the CMS Enterprise Portal (https://portal.cms.gov). Click "Login to CMS Secure Portal" and enter your EIDM credentials.

2. Accept the Terms and Conditions.

3. To establish access to HIOS through the CMS Enterprise portal, click "Request Access Now." From the Access Catalog, click "Request Access" for the HIOS application.

4. From the My Access page, click "Request New System Access" and select "HIOS – HIOS Application" from the System Description dropdown menu and "HIOS Issuer" for the Role. New users will need to click the hyperlink provided on the page to register for HIOS access. Navigate to the HIOS registration page using the URL provided and complete the HIOS user registration process.

5. Once the HIOS user registration request has been reviewed and approved, an email containing the HIOS Authorization Code will be provided. Users will need to enter the HIOS Authorization Code to obtain access to HIOS (see Step 6 below).

6. Repeat steps 3 and 4 in the CMS Enterprise Portal, but do not click the HIOS account request hyperlink this time. On the "Request New System Access" page, enter the HIOS Authorization Code and then click "Submit". This concludes the EIDM function. For CMS Enterprise Portal login issues, users can call the Exchange Operations Support Center at 1-855-267-1515 or email CMS_FEPS@cms.hhs.gov.

7. Log out of the CMS Enterprise Portal and log back in. Users should see a yellow "HIOS" button on the top left of the dashboard indicating successful access established to HIOS.

8. Click the yellow HIOS button, followed by the "Access HIOS" or the "Access Plan Management and Market Wide Functions" link to access HIOS functionality.

iii. HIOS Organization Registration:

1. Click the "Manage an Organization" button on the HIOS Home Page.

2. From the drop-down list, select "Create new organization".

3. Select the Organization Type from the drop-down list.
NOTE: There is a hyperlink to a list of organization types and their definitions to help the user decide which organization type to create. Provide a Federal EIN/TIN in order to conduct a search to determine if the organization currently exists in HIOS. If the organization does not have a FEIN, the user can enter the organization name and click "Search".

4a. If an organization does not exist, users will need to register the organization by clicking the "Create Organization" button and enter the organization's information.

4b. If an organization exists, information will be displayed on the page. Users have the option to click "Add Issuer" and proceed to the "Register New Issuer" page. Complete the form with the Issuer's information and click the "Save and Add Another Issuer" button. Click "Submit" and a New Issuer Confirmation page will display.

5. Users receive an email notification once the registration request has been reviewed and approved.

b. Existing HIOS Users

i. HIOS Role Management: Once the organization has been successfully registered, users can request a role(s) for the HIOS module(s).

1. Click the "Role Management" button on the HIOS Home Page.

2. Click the "Request Role" tab and select the desired Module, Requested Role, User Type, and User Sub-Type. Click "Continue" to proceed.

3. Enter the Organization identifier (Organization Name, FEIN, Issuer ID, or State) and click "Search." Click the "Review/Continue" button and proceed to submit the role request.

4. Users receive an email notification once the role request has been reviewed and approved.

NOTE: To see user role(s) and access permissions, click the "View Existing Role" tab.

A copy of the HIOS Document Collection Form Filing Module Technical Guide is available for download once you access the Document Collection Form Filing Module in HIOS. Please note, submission for Large Group products may need to be added as a New Product. See the HIOS Document Collection Form Filing Module Technical Guide starting on page 24, Section 5.2, for instructions on who to add these products in the HIOS Form Filing Module. If you have any questions regarding accessing HIOS, please contact the help desk at CMS_FEPS@cms.hhs.gov or 1-855-CMS-1515.

Operationally, the HIOS Document Collection Form Filing module only allows issuers to add products in the Large Group market; it prohibits issuers from adding products in the Individual/Small Group markets (an error message is displayed to the user). Users should continue adding Individual and Small Group market products within the HIOS Plan Finder Product Data Collection Module.

a. From the HIOS Portal, select "HIOS Plan Finder Product Data Collection Module" button.

b. Select the "View Issuer Submitted Data: tab.

c. Select the "Product Offering Report" link.

d. To create a new product, select the "Add New Product" link to get a blank product entry window. A new Product ID will be automatically generated once the user selects Submit.

B. RATE FILING

1. For which plans must rate filings be submitted?

Health insurance issuers filing in Direct Enforcement states[2] are required to submit rate filings for new or renewal rates effective on or after January 1, 2017, for all non-grandfathered plans in either the individual or small group markets. Rate filings will be reviewed for compliance with the market reform rules under the PHS Act and the Affordable Care Act, including rating rules and the single risk pool requirements, as applicable.

[2] Direct Enforcement states are currently Missouri, Oklahoma, Texas, and Wyoming. These states also do not currently have an effective rate review program; therefore, CMS will review rate increases subject to review in these states to determine whether they are is unreasonable, as required by 45 CFR Part 154.

2. What documents need to be submitted?

Issuers of single risk pool plans[3] must submit a Rate Filing Justification into the HIOS Unified Rate Review (URR) Module which generally consists of Part I – Unified Rate Review template, the Part II – Written Description Justifying the Rate Increase (required for rate increases of 10% or more), and Part III – Rate Filing Documentation (Actuarial Memorandum).

Issuers of non-single risk pool plans[4] must submit a Preliminary Justification for any rate increases of ten percent or greater into the HIOS Rate Review Justification (RRJ) Module which generally consists of Part I – Rate Increase Summary Form, the Part II – Written Explanation of the Rate Increase, and Part III – Rate Filing Documentation. For any rate increases less than ten percent, issuers of non-single risk pool plans are required to submit into the HIOS RRJ Module Part I and Part III. Part II is not required, and issuers may make a statement to that effect in the Part II text box.

3. When do required documents need to be submitted?

The rate filing documents for single risk pool plans must be submitted into the HIOS URR Module beginning on April 11, 2016 but no later than the deadline specified in CMS's 2017 Letter to Issuers in the Federally-facilitated Marketplaces.[5] For quarterly rate update submissions in the small group market, the deadline is 105 days prior to the effective date of the quarterly change. If the single risk pool includes a QHP offered in the Federally-facilitated SHOP, issuers should be mindful of the data correction windows when a revised Rate Table Template must be submitted.

The rate filing documents for non-single risk pool plans must be submitted in to the HIOS RRJ Module. Issuers are encouraged to submit the Preliminary Justification at least 60 days in advance of implementation of the rate increase.

4. When are premiums published?

CMS publishes new rates/premiums on our websites 45 days prior to the effective date of the change.

5. What if issuers have questions about rate filing submissions?

For questions regarding submission of rate filing documents, please contact the rate review team by email at RateReview@cms.hhs.gov.

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[3] For purposes of the requirements established in 45 CFR Part 154, "single risk pool plan" is used to refer to non-grandfathered health insurance coverage in the individual or small group (or merged) market that is subject to all of the single risk pool provisions at 45 CFR 156.80.

[4] For purposes of the requirements established in 45 CFR Part 154, "non-single risk pool plan" is used to refer to non-grandfathered student health plans.

[5] The draft 2017 Letter to Issuers in the Federally-facilitated Marketplaces (FFMs) provides for a May 11, 2016 deadline; available at https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Draft-2017-Letter-to-Issuers-12-23-2015_508.pdf.