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Title: Insurance Standards Bulletin Series – INFORMATION

Subject: CCIIO Sub-Regulatory Guidance: Updated Procedures and Requirements for HIPAA Exemption Election through the Health Insurance Oversight System (HIOS)

I. Purpose

The final regulations at 45 CFR 146.180 refer to a replacement format by which sponsors of self-funded, non-Federal governmental plans are permitted to elect to exempt those plans from (“opt out of”) certain provisions of title XXVII of the Public Health Service (PHS) Act.¹ The preamble states that CMS will replace the mailing address for submitting opt-out documents and that opt-out elections must be submitted in an electronic format as specified by the Secretary in guidance. This memorandum constitutes guidance regarding that process.

II. Opt-out Election for Self-funded, Non-Federal Governmental Plans

Prior to enactment of the Affordable Care Act, sponsors of self-funded, non-Federal governmental plans were permitted to elect to exempt those plans from certain provisions of title XXVII of the PHS Act. Such elections were authorized under section 2721(b)(2) of the PHS Act. Sponsors of those plans could elect to opt out of all or any of the following title XXVII requirement categories:

1. Limitations on preexisting condition exclusion periods under section 2701 of the PHS Act (redesignated as section 2704 by the Affordable Care Act).
2. Requirements for special enrollment periods under section 2701 of the PHS Act (redesignated as section 2704 by the Affordable Care Act).
3. Prohibitions against discriminating against individual participants and beneficiaries based on health status (but not including provisions added by the Genetic Information Nondiscrimination Act of 2008) under 2702 of the PHS Act (redesignated as section 2705 by the Affordable Care Act).

¹ 79 FR 30240 (May 27, 2014).

4. Standards relating to benefits for newborns and mothers under section 2704 of the PHS Act (redesignated as section 2725 by the Affordable Care Act).
5. Parity in the application of certain limits to mental health and substance use disorder benefits (including requirements of the Mental Health Parity and Addiction Equity Act of 2008) under section 2705 of the PHS Act (redesignated as section 2726 by the Affordable Care Act).
6. Required coverage for reconstructive surgery following mastectomies under section 2706 of the PHS Act (redesignated as section 2727 of the PHS Act).
7. Coverage of dependent students on a medically necessary leave of absence under section 2707 of the PHS Act (redesignated as section 2728 by the Affordable Care Act).

The Affordable Care Act amended the PHS Act. As a result, self-funded, non-Federal governmental plans can no longer opt out of certain requirements of title XXVII. First, PHS Act section 2721 was redesignated as section 2722. The new section 2722(a)(2) no longer allows a sponsor of a self-funded, non-Federal governmental plan to exempt that plan from requirement categories 1-3 listed above, but continues to allow the sponsor to exempt the plan from requirement categories 4-7.

In response to the Affordable Care Act amendments, HHS issued guidance on September 21, 2010 indicating that, for plan years beginning on or after September 23, 2010, plan sponsors of non-collectively bargained plans can only elect to be exempted from provisions 4-7 and that provisions 1-3 are no longer available for exemption.² Group health plans maintained pursuant to a collective bargaining agreement that was ratified before March 23, 2010, and that have been exempted from any of the first 3 requirement categories listed above, would not have to come into compliance with those provisions until the commencement of the first plan year following the expiration of the last plan year governed by the collective bargaining agreement. Because of the timing of the guidance, HHS elected not to take any enforcement actions with respect to opt-out elections for plan years beginning prior to April 1, 2011 for categories 1-3 listed above.

On May 27, 2014, CMS published the final regulation addressing the Health Insurance Portability and Accountability Act (HIPAA) opt-out election process (79 FR 30240). The regulation reiterated what was stated in the September 21, 2010 guidance and added a requirement for elections of group health plans subject to collective bargaining: that while only one election is required for all of the group health plans subject to the agreement, the names of all group health plans covered by the election must be listed in the election document. A clarification was also added to the final rule stating that sponsors of multiple group health plans not subject to collective bargaining will have to submit a separate election for each group health plan that wishes to be exempt from any of the four provisions. The final regulation also indicated that hard copy election documents via U.S. mail or facsimile will only be accepted through

² Amendments to the HIPAA opt-out provision (formerly section 2721(b)(2) of the Public Health Service Act) made by the Affordable Care Act (September 21, 2010). Available at: http://www.cms.gov/CCIIO/Resources/Files/Downloads/opt_out_memo.pdf.

December 31, 2014, after which only elections submitted through electronic submission will be accepted.

III. Requirements for Opt-out Elections

An opt-out election for a self-funded, non-Federal governmental plan must meet the following requirements:

- Be made in an electronic format, as described in this guidance. As indicated in the final regulation, hard copy elections will not be accepted after December 31, 2014;
- Be made in conformance with all the plan sponsor's rules, including any public hearing requirements;
- Specify the beginning and end dates of the period to which the election is to apply. This period can be either a single specified plan year as defined in 45 CFR 144.103 or the “term of the agreement” as specified in 45 CFR 146.180(b)(2);
- Specify the name of the plan and the name and address of the plan administrator, and include the name and telephone number of a person CMS may contact regarding the election;
- State that the plan does not include health insurance coverage, or identify which portion of the plan is not funded through health insurance coverage;
- Specify each requirement from which the plan sponsor elects to exempt the plan;
- Certify that the person signing the election document, including (if applicable) a third party plan administrator, is legally authorized to do so by the plan sponsor;
- For initial elections, include as an attachment, a copy of the notice to plan enrollees; and,
- For renewal elections, in lieu of attaching a copy of the notice, certify that the notice has been, or will be, provided to enrollees as specified under 45 CFR 146.180(e).

IV. Electronic Submission of Opt-out Elections

In lieu of submitting opt-out elections via U.S. Mail or facsimile, a plan sponsor must submit opt-out elections through the Non-Federal Governmental Plans Module (Non-Fed Module) in the Health Insurance Oversight System (HIOS).

To begin this process, plan sponsors will need to register for access to HIOS, request access to the Non-Fed Module, and choose the user role for their submission. One of the two mutually exclusive user roles must be selected: (1) a Role Approver Administrator who confirms Submitter role requests, or (2) the Submitter, who completes the application and submits the documents. Plan sponsors should register the Role Approver Administrator role in HIOS prior to registering the Submitter role in the Non-Fed Module. Once the Role Approver Administrator is registered, they can approve the Submitter role. The Submitter can then access the Non-Fed Module to complete the application and submit the documents.

The following steps for registering users for the Non-Fed Module apply to both roles, and differ based on whether the user previously registered for HIOS:

- a. New HIOS users:

- i. New HIOS users will need to use the Enterprise Portal to register in Enterprise Identity Management (EIDM) system at <https://portal.cms.gov> before they can become a HIOS user. Click on “New User Registration” in the right hand column of the web page under “Login to Secure Portal” and follow the instructions. Users will receive an email confirmation that registration has been completed, along with their EIDM User ID.
 - ii. Once the user receives an EIDM User ID, the user should log back into EIDM, <https://portal.cms.gov>, using their EIDM User ID and password. Click on the “Login to CMS Secure Portal” button in the right column of the webpage. Click on the “Request Access Now” link on the right column of the webpage. Select HIOS from the “Application Description” dropdown box. New users will need to register in HIOS by clicking the link at the bottom of the page and following the registration instructions. Once the HIOS registration has been approved, the user will receive an email with their HIOS information and an Authorization Code.
 - iii. The user will need to log into EIDM at <https://portal.cms.gov> and click on the “Login to CMS Secure Portal” button in the right column. Click on the “My Access” button to “Request New Application Access” and choose “HIOS.” Enter the HIOS Authorization Code provided in the confirmation email and follow the instructions.
 - iv. The user will need to log out of EIDM then log back in to EIDM at <https://portal.cms.gov> and navigate to the HIOS tab.
 - v. Once the user navigates to the HIOS tab, they will click the “Access HIOS” link and request access to the HIOS Non-Fed Module by navigating to “Role Management.” Follow the instructions to complete the request. If the user cannot locate their organization within “Role Management,” they should navigate to the “Manage Organization” page on the HIOS home screen and follow the instructions to register the organization in HIOS. After successful organization registration, the user may request the appropriate role within the HIOS Non-Fed Module.
- b. Existing HIOS Users:
- i. Existing HIOS users should log in to EIDM at <https://portal.cms.gov> and navigate to the HIOS tab. Once the user navigates to the HIOS tab, they will click the “Access HIOS” link and request access to the HIOS Non-Fed Module by navigating to “Role Management.” Follow the instructions to complete the request. If the user cannot locate their organization within “Role Management,” they should navigate to the “Manage Organization” page on the HIOS home screen and follow the instructions to register the organization in HIOS. After successful organization registration, the user may request the appropriate role within the HIOS Non-Fed Module.

After completing the online request, both types of users will receive an email notification when access has been approved. Again, please note: while Role Approval Administrators role requests are approved through HIOS, Submitter role requests are subject to the additional step of requiring approval by a Role Approval Administrator in the organization. Once your organization has been registered, users can create their submission. A copy of the Health Insurance Oversight System (HIOS) Non-Federal Governmental Plans User Manual is available for download once you access the Non-Fed Module in HIOS. If you have any questions regarding accessing HIOS, please contact the help desk at CMS_FEPS@cms.hhs.gov or 1-855-CMS-1515.

V. Certification

Plan sponsors submitting an election must provide a certification by entering their electronic signature which includes title, first name, and last name. Please ensure that the individual signing the certification conducts a thorough review of the election contents and is fully aware of the information and representations to which he or she is certifying. Also, **the individual signing the certification should be the Non-Fed Module Submitter for the online HIOS submission.**

VI. Submission

A complete election consists of: (1) the election document; (2) a signed certification; and (3) if required, a copy of the notice of election to plan enrollees. Only electronic applications will be accepted via HIOS after December 31, 2014. A copy of the notice will be accepted only in Word or PDF format.

HIPAA opt-outs for collectively bargained plans may be submitted as “New” or “Renewal” opt-outs in HIOS. Such elections may only opt out of provisions 4-7 as stated in section II, above. The opt-out cannot be submitted as a renewal if the collectively bargained plan had not previously only opted out of provisions 4-7 and would like to opt out of one of those provisions.

VII. Notice

A plan that makes an election pursuant to 45 CFR § 146.180 must comply with the notice requirement in 45 CFR § 146.180(e). Plans must notify each affected enrollee in writing of the election and explain the consequences of the paragraph using model notice language, or by complying with the requirements in section 45 CFR § 146.180(e)(3)(i)-(iv). The plan will be in compliance with this requirement if it prints the notice prominently in the summary plan description or equivalent description provided to enrollees at the time of enrollment and annually. Notices can be delivered by e-mail if the plan sponsor meets the criteria of the Department of Labor electronic disclosure safe harbor at 29 CFR 2520.104b-1(c). Initial notices must be provided prior to the first day of that plan year, and renewal notices must be provided no later than the last day of each plan year. The CMS model notice can be accessed via: https://www.cms.gov/CCIIO/Resources/Files/Downloads/model_enrollee_notice_04072011.pdf

New opt-out submissions must provide a copy of the notice with the election document. Renewal opt-out submissions must certify that notice has been sent.

VIII. Timing

Plans not governed by a collective bargaining agreement must file an election with CMS before the first day of the plan year. Plans governed by a collective bargaining agreement must file an election with CMS before the first day of the plan year, or by the 45th day after the latest applicable date specified in 45 CFR § 146.180(b)(2)(i) if the 45th day falls on or after the first day of the plan year.

Where to get more information:

If you have any questions regarding this Bulletin, please contact CMS via e-mail at HIPAAOptOut@cms.hhs.gov.

For more detailed technical information, please see the HIOS Non-Federal Governmental Plans User Manual, which can be accessed via: <https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/HIOS-NonFed-UserManual.pdf>