**December 1, 2016:**

**Call Summary and Action Item Follow-up**

**Industry & CMS**

**Preclusion List Requirements**

Outlined below is a summary of the discussion and action items from the call of December 1, 2016.

Based on the November 9, 2016 meeting summary, a major portion of the discussion focused on the impact of the application of the Preclusion file to Medicare, but not Medicaid, and the implications of this limitation.

1.) Preclusion and Exclusion files

Industry provided the following explanation and expressed the identified additional concerns:

* Limiting the Preclusion file to Medicare only represents a major change from the process currently used in processing OIG Exclusion file denials which apply to both Medicare and Medicaid.
* Limiting the Preclusion file to Medicare only significantly impacts the dual eligible programs.
* To better understand the impact of limiting the Preclusion file to Medicare only, CMS should clarify prioritization, cost sharing, and applicable coverage limitations when the drug is not covered by Medicare but is covered by Medicaid.
* Since the Exclusion file requires a specific beneficiary notification process, plans/PBMs need guidance on whether a separate letter will be required for beneficiaries whose prescribers are on the Preclusion List. Further guidance is also requested on the appeals process.

CMS stated the prescribers on the Preclusion file are not enrolled in Medicare and therefore should be handled in accordance with the HPMS December 27, 2015 Plan guidance page 27. (Separately CMS will have an internal discussion on the elements of the Guidance that may be applicable in general.)

Industry asked that CMS further explain the differences between the Exclusion and the Preclusion files and explain why the two files cannot be handled in the same manner by the plans/PBMs.

* CMS explained that, in reference to the Exclusion file, OIG has the statutory authority to exclude providers from both Medicare and Medicaid.
* The Preclusion file cannot be applied in the same manner because different statutory and regulatory authorities are applicable. The Preclusion file includes revoked prescribers, or non-enrolled prescribers who have been convicted of a felony within the past ten years. The regulations specifically limit the extent to which Medicare’s revocation (or other) authority can be applied to Medicaid prescribers.

Preliminarily, plans/PBMs indicated that applying the Preclusion file to Medicare only could delay the Preclusion file implementation from two to twelve months while system changes are made. To allow the plans/PBMs to further understand the differences and similarities between the Exclusion and the Preclusion files, CMS has provided a comparison flow chart to detail how providers on each list are to be handled operationally. (See Attachment 1). This information should allow plans/PBMs to better assess the level of effort required to implement the Preclusion file requirements. Plans/PBMs are expected to respond to CMS with level of effort estimates by mid-January 2017.

2.) Preclusion File Characteristics

* The file layout should be the same as the Exclusion file.
* The Preclusion file will be a new, separate file which will be placed in the same location as the Exclusion file.
* In terms of whether a provider should be on one or both lists, it was noted that prescribers may be removed from the Exclusion file but remain on the Preclusion file because the Exclusion file time periods and Preclusion file time periods are not always the same.
* CMS will continue to investigate adding date(s) fields to the Preclusion file.
* CMS also noted the Preclusion file is expected to be a monthly replacement file.

3.) Test File Availability

* Industry agreed that production of the test Preclusion file that was originally projected to be available in January 2017 should be delayed.

4) Comments on the November 9, 2016 Meeting Summary

* The due date for comments/responses was moved to December 9, 2016.

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| **December 1, 2016 Action Item List** | **Assigned** | **Completion Date** |
| 1. To better understand the impact of limiting the Preclusion file, CMS should clarify prioritization, cost sharing, and applicable coverage limitations when the drug is not covered by Medicare but is covered by Medicaid. CMS stated the prescribers on the Preclusion file are not enrolled in Medicare and therefore should be handled in accordance with the HPMS December 27, 2015 Plan guidance page 27. Separately CMS will have an internal discussion on the elements of the Guidance that are generally applicable. | CPI/CM |  |
| 1. Since the Exclusion file requires a specific beneficiary notification process, PBMs need guidance on whether a separate letter will be required for beneficiaries whose prescribers are on the Preclusion file. Further guidance was also requested on the appeals process for Preclusion denials. Additionally, guidance was requested on processing medical and related services and supplies provided by plan network prescribers when the prescriber is on the Preclusion file. | CPI/CM |  |
| 1. To allow the plans/PBMs to further understand the differences and similarities between the Exclusion and the Preclusion files, CMS agreed to provide a descriptive comparison flow chart to detail how providers on each list are to be handled operationally. | CPI | 12/12/2016 |
| 1. CMS will continue to investigate adding date(s) fields to the Preclusion List file. | CPI |  |
| 1. Comments on the November 9, 2016 Meeting Summary: The due date for comments/responses has been moved to December 9, 2016. | Industry | 12/9/2016 |
| 1. Plans/PBMs are expected to respond to CMS with level of effort estimates by mid-January 2017. [1/13/2017] | Industry |  |