

Stakeholder/OIRA Meeting to Discuss Notice and Tagline Requirements
May 9, 2018 / 10:00 a.m. (ET)

New Executive Office Building
725 17th Street, NW
Room 9276

- I. Introductions**
- II. Background/Overview of Issues**
- III. Resources Highlighting Issues Related to the Notice and Tagline Requirements**
- IV. Recommendations**

Cost Impact Analysis of the Nondiscrimination Notices

Background

On May 18, 2016, the Office of Civil Rights (OCR) published the final rule implementing Section 1557.¹ This final rule codified the notice and tagline requirements (hereinafter referred to as the “nondiscrimination notices”) at 45 C.F.R. § 92.8 and provides, in part, as follows:

§92.8(f)(1) Each covered entity shall post the notice [. . .] and the taglines [. . .] in a conspicuously-visible font size:

(i) *In significant publications and significant communications* targeted to beneficiaries, enrollees, applicants, and members of the public, except for significant publications and significant communications that are small-sized, such as postcards and tri-fold brochures...

(Emphasis added.) Although the text of the regulations refers to “significant publications,” neither the regulation nor the Preamble define what constitutes “significant.” Instead, OCR defined “significant” through sub-regulatory guidance in the form of a series of FAQs that were published on the agency’s website.² The agency did not engage in any formal notice-and-comment rulemaking in the course of issuing these FAQs.

The resulting burden imposed upon pharmacy benefit managers (PBMs) by the nondiscrimination notices is estimated to cost the industry between \$500 million to nearly \$5 billion this year, despite zero evidence of their effectiveness.³

OCR requested that we provide greater detail on the cost burden imposed upon PBMs as result of the nondiscrimination notice requirements.

Data and Methodology

PCMA solicited its member companies to provide data on the costs associated with the nondiscrimination notice requirements.

We received data from member companies representing over two thirds of all PBM lives.

1. Communication Volume

PBMs administer prescription drug benefits and operate specialty pharmacies for more than 266 million Americans with health coverage, including coverage in the Medicare, Medicaid, and the

¹ “Nondiscrimination in Health Programs and Activities,” 81 Fed. Reg. 31375 (May 18, 2016).

² “Section 1557: Frequently Asked Questions,” Question 26 (accessed March 29, 2017), *available at* <https://www.hhs.gov/civil-rights/for-individuals/section-1557/1557faqs/>

³ These costs are in direct contradiction to the OMB cost estimates which provided for “no resource costs related to including updated notices in the publications.” “Nondiscrimination in Health Programs and Activities; Final Rule,” 81 Federal Register 31,376, 31,453 (May 18, 2016).

health insurance marketplaces established by the Affordable Care Act (ACA). Collectively PBMs process over three billion prescriptions a year, roughly 12 prescriptions per beneficiary.

In addition to processing drug transactions, PBMs engage with beneficiaries regarding their prescription drug activity, including but not limited to prescription drug refill reminders, mail order prescriptions, and drug safety information. These often take the form of notices. Furthermore, federal and state regulators require PBMs to issue more than 40 separate notices to beneficiaries regarding their membership activities and contractual changes (see Appendix 1 for a sample list of beneficiary communication). For example, in the Medicaid program, beneficiaries receive an average of 16 notices per year, while Medicare beneficiaries receive a minimum of six notices to more than 28 notices a year depending on their level of drug utilization.

Given the various types of pharmacy and member-related communications, we estimate that that PBMs mail approximately 1 to nearly 5 billion notices over a 12-month period depending on their patient mix, their level of drug utilization and the federal or state requirement regarding beneficiary communication (see Table 1).

Table 1: Annual Volume of Communication Requiring Nondiscrimination Notices

| Range | Estimated number of Beneficiaries Impacted by the Nondiscrimination Notice⁴ | Average Number of Communications per Beneficiary per Year^{5,6} | Total Number of Communications Requiring Nondiscrimination Notice Per Year |
|--------------|---|--|---|
| Low | 173 Million | 6 | 1.0 Billion |
| Medium | 173 Million | 17 | 2.9 Billion |
| High | 173 Million | 28 | 4.8 Billion |

2. Cost Impact

We estimate the annual cost to produce and print the notices, including the development costs for the materials and the operational costs associated with longer print times to range from \$0.50 to \$1.00 per notice depending on size of the communication, resulting in an annual industry cost of \$518 million to \$5 billion (see Table 2).⁷

Table 2: Cost of Nondiscrimination Notices

⁴ Assumes that roughly 65 percent of total PBM beneficiaries are impacted by the nondiscrimination notice requirements.

⁵ PBMs mail between 6 - 28 notices per beneficiary per year depending on their drug utilization and program requirements. The low range assumes beneficiaries receive six notices/year; the medium range assumes beneficiaries receive 16 notices/ year; the high range assumes that beneficiaries receive 28 notices/ year.

⁶ This does not include notices that are mailed with the original prescription.

⁷ Does not include the cost of increased postage, which may result in some cases.

| Range | Total Number of Communications Requiring Nondiscrimination Notice | Cost Per Notice | Total Annual Spend |
|--------------|--|------------------------|--------------------------------|
| Low | 1.0 Billion | \$0.50 - \$1.00 | \$518 Million to \$1.0 Billion |
| Medium | 2.9 Billion | \$0.50 - \$1.00 | \$1.5 to 2.9 Billion |
| High | 4.8 Billion | \$0.50 - \$1.00 | \$2.4 to 4.8 Billion |

Summary

As we have noted to OCR many times, the burdens and costs associated with the nondiscrimination notices are particularly acute for PBMs, which handle millions of claims, operate in many different states, and thus face multiple, diverse tagline requirements across their portfolio of plans. Further, because of the quantity of drug benefit transactions and utilization decisions, the costs of developing and printing the notices and developing new web-content for taglines are vastly burdensome for PBMs.

Appendix 1: Sample List of Beneficiary Communication *(representative only, list is not exhaustive)*

| Communication |
|--|
| Appeals letters |
| Adverse Benefit Determinations |
| Annual enrollment/renewal packages |
| Coordination of Benefits member communications |
| Customer Service related letters |
| Coverage review & determination letters |
| Formulary change notices |
| Formulary alternative notices (generic medication education) |
| Grievance letters |
| Home delivery benefit letters |
| Specialty benefit letters |
| Member submitted claims letters |
| Member Invoices & Refunds |
| Part D Model Doc: Annual Notice of Change (ANOC) |
| Part D Model Doc: Transition Letters |
| Part D Model Doc: Eligibility Notices (~65 different notices) |
| Part D Model Doc: Errata (correction) notices |
| Part D Model Doc: Explanation of Benefits (EOB) |
| Part D Model Doc: Evidence of Coverage (EOC) |
| Part D Model Doc: Excluded/OIG Sanctioned Provider Letters |
| Part D Model Doc: Formulary Guidebook |
| Part D Model Doc: Low Income Subsidy Premium Summary |
| Part D Model Doc: Low Income Subsidy Rider |
| Part D Model Doc: Pharmacy Directory |
| Part D Model Doc: Medication Therapy Management (MTM) letters |
| Part D Model Doc: ID Cards |
| Pharmacy letters – i.e. auto-ship, refill reminders |
| Preferred retail pharmacy network letters |
| Network Change Notice |
| Notice of Creditable Coverage |
| Pharmacy Termination Notices |
| Plan Change Notice |
| Prescription Benefit Review (explanation of benefits for non-Medicare beneficiaries) |
| Safety Alerts – i.e. drug utilization review, duplicate therapy |
| Summary of Benefits |
| Specialty benefit letters |
| Utilization Management letters (step therapy, quantity limits, prior authorization) |
| Vaccine Administration letters |

Anti-Discrimination Requirements

Pre – 1557 and Post 1557

| Area Regulation Source | Non Discrimination Notice | Tag Lines | Meaningful Access (LEP) |
|-----------------------------------|--|--|---|
| Rehabilitation Act Section 504 | appropriate and continuing steps to notify; does not discriminate; notification methods <i>may</i> include publication in newspapers, memo, or other written communications; | No independent requirements | No independent requirement |
| Civil Rights Act of 1964 Title VI | make information available to apprise persons of the protections against discrimination | Flexibility in achieving requirements | Flexibility in achieving requirements balancing four key factors |
| Age Act | Make information available to inform individuals of the protections against discrimination | No independent requirement | No independent requirement |
| Medicare Part D | No independent requirement | Multi-Language insert – 5% rule | Interpreter services available, regardless of %. Written translations representing 5% for enrollment materials, TF letter, and STAR ratings |
| OCR 1557 | Post notice with seven required elements, and include in all significant documents | Top 15 languages spoken in area; post on all significant documents | Offer interpreter services; qualified translator when translating written materials |

BREADTH OF DOCUMENTS THAT MUST RECEIVE DISCRIMINATION NOTICE GREATLY EXPANDED - PRE 1557 "MAKE AVAILABLE". POST 1557 MUST POST AND BE INCLUDED IN ALL SIGNIFICANT DOCUMENTS

BREATH OF LANGUAGES GREATLY EXPANDED PRE 1557 – 5% POST 1557 – TOP 15 AND INCLUDED ON ALL DOCUMENTS

Notice and Tagline Complaints (April 2017)

Sample from Two PBM's

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| <ul style="list-style-type: none"> Beneficiary is upset about what she believes to be a waste of paper included in her billing invoices, that are received monthly. Believes that the language pages should not be sent to her nor her husband due to her not speaking other language besides English. |
| <ul style="list-style-type: none"> Member states that she is upset that her letter with her new ID card included many other languages which she cannot understand and she would like for all letters in the future to be in English if the member speaks English |
| <ul style="list-style-type: none"> BENEFICIARY IS DISSATISFIED WITH THE FOLLOWING ISSUE(S): 1) MEMBER STATED THAT HE RECENTLY RECIEVED HIS EXPLANATION OF BENFEITS COPY AND DOES'NT FIND IT NECESSARY THAT ADDITIONAL PAPERS ARE BEING PRINTED FOR LANGUAGE OPTIONS. |
| <ul style="list-style-type: none"> "x" called because he received a letter that had like 40 different languages listed. Member did not understand what the letter about and thought something bad was going to happen because there were so many different languages listed. Member was very upset that not only did he not understand the English part but also why there was so many languages on the letter. |
| <ul style="list-style-type: none"> Member called in and was upset that we sent her out a letter of non-discrimination and listed in all 64 languages that "if needed, a language interpreter will be provided to you at no cost". She believes that if you live in America, you should at least be able to read that in English and does not feel like it is necessary for us to translate one sentence 64 times in all languages available. She said our company is wasting time and material. |
| <ul style="list-style-type: none"> Member receives too many flyers that are very hard to understand. Member dislikes receiving pages of information that he doesn't read or think are necessary. For example, he was sent a flyer about multiple languages that are offered, but doesn't think it's necessary to notify him of that. |
| <ul style="list-style-type: none"> Plan reviewed the Beneficiary's complaint and identified the following issue (s): 1. Beneficiary writes he is very offended by the different language forms provided by the plan. |
| <ul style="list-style-type: none"> Member just received a bill today 3/03/17 of the amount due for 3mths. She has not received noticed before. It was quite a shocking to see the amount due and would have taken care of the balance in a timely manner had she received it the invoice monthly. Member also does not like that she receive 2 extra pages with foreign language- she does not need that and we need to stop and save the trees. |
| <ul style="list-style-type: none"> Member state the language papers needs to stop (it's a waste of paper and ink) wife("x") and husband ("x") would like it to stop (plus medication being covered) |
| <ul style="list-style-type: none"> Plan reviewed the Beneficiary's complaint and identified the following issue (s): 1. Beneficiary is dissatisfied with the plan information she is receiving interpreters for foreign speakers. she states do not punish English speakers by raising premiums. |
| <ul style="list-style-type: none"> Beneficiary is annoyed with the disclaimer that is sent every month using a whole piece of paper to provide the disclaimer in every language. |
| <ul style="list-style-type: none"> Member calling about extra paper that is being sent in for his Explanation of Benefits. Every month 65 different languages are listed at the bottom of the EOB. Member doesn't want the excessive paper when the information is coming in the correct language of English. |
| <ul style="list-style-type: none"> Plan reviewed the member's complaint and identified the following issue (s): 1. The member requested that the Plan either send the non-discrimination policy either once a year or electronically as the member feels it is a waste of paper. 2. The member indicated that she no longer wants to receive this correspondence in the mail and requests to be opted out. |
| <ul style="list-style-type: none"> Issues: 1. Member does not want to receive the Discrimination Notice with every mailing she receives. 2. Member states the Discrimination Notice is a huge waste of paper to be mailed with everything she receives. |
| <ul style="list-style-type: none"> "x" called to complain about the letters she receives every month about the languages and that it comes in several different languages and every month. Member finds it a waste |

Table 1. Nondiscrimination Notice Communication Impact ListReal World Single PBM Impact¹

| Communication | Proj'd Annual Volume | Proj'd Annual Print Cost |
|--|-----------------------------|---------------------------------|
| COB Payer member communications (OHI) | 42,908 | \$3,004 |
| Customer Service | 100,000 | \$7,000 |
| Enrollment Kit: Enrollment brochure, Enrollment Form, Summary of Benefits, Star Ratings Form | 60,642 | \$4,245 |
| Explanation of Payment and Notice of Denial | 870,000 | \$60,900 |
| Errata Notices | 17,300 | \$1,211 |
| Home Delivery letters | 4,000,000 | \$280,000 |
| Specialty letters | 27,500 | \$1,925 |
| Explanation of Benefits/Prescription Benefit Review (non-Medicare) | 790,000 | \$55,300 |
| Formulary Change Notices | 30,500 | \$2,135 |
| Manual Claim letters | 25,400 | \$1,778 |
| Medicaid Overcharge Apology | 68,500 | \$4,795 |
| Medicaid QLL UM | 1,700 | \$119 |
| Member Recovery (Open balance, refund due, etc.) | 680,000 | \$47,600 |
| Part D Model Doc: Annual Notice of Change (ANOC) | 2,450,000 | \$171,500 |
| Part D Model Doc: CY 2017 Model Transition Letter | 1,200,000 | \$84,000 |
| Part D Model Doc: Eligibility Notices (~65 notices for PDP - Exhibit Letters) | 685,500 | \$47,985 |
| Part D Model Doc: EOB | 35,200,000 | \$2,464,000 |
| Part D Model Doc: Evidence of Coverage (EOC) - Member Request | 1,000 | \$70 |

¹ Note that the numbers here are real world numbers from one of our members. The costs are only indicative of print cost and do not include the one time development costs for these materials (approximately \$2 million), nor does it include the operational costs associated with longer print times (approximately \$4 million annually).

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|---|-------------------|-----------------------|
| Part D Model Doc: Excluded Provider | 3,200 | \$224 |
| Part D Model Doc: Formulary - Member Request | 3,000 | \$210 |
| Part D Model Doc: LIS Premium Summary | 1,000 | \$70 |
| Part D Model Doc: Low Income Subsidy (LIS) Rider - Member Request | 1,000 | \$70 |
| Part D Model Doc: Pharmacy Directory | 5,000 | \$350 |
| Part D Model Doc: Welcome Kit /Group Transfer Letters | 32,500 | \$2,275 |
| Part D Model Doc: ID Card Replacements | 150,000 | \$10,500 |
| Network Change Notice | 50,000 | \$3,500 |
| Notice of Creditable Coverage | 2,000 | \$140 |
| Pharmacy Termination Notices | 305,000 | \$21,350 |
| Plan Change Notice | 140,000 | \$9,800 |
| Pre-Notification Package (Letter and Benefit Overview) | 155,000 | \$10,850 |
| Safety Alerts | 130,600 | \$9,142 |
| Reviews & Appeals Letters | 6,500,000 | \$455,000 |
| OIG Sanction Campaign Letters | 120 | \$8 |
| Summary of Benefits - Post Enrollment | 10,100 | \$707 |
| Transition letters | 1,200,000 | \$84,000 |
| Vaccine Admin Letter (Medicare) | 2,925 | \$205 |
| Welcome Kits | 532,000 | \$37,240 |
| Total Communications | 55,474,395 | \$3,883,207.65 |